

- VOLUME 8 -
IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,	CIVIL ACTION
Plaintiff	
vs.	
MEDTRONIC AVE, INC., et al.,	NO. 97-550 (SLR)
Defendants	
MEDTRONIC AVE, INC.,	CIVIL ACTION
Plaintiff	
vs.	
CORDIS CORPORATION, et al.,	NO. 97-700 (SLR)
Defendants	
CORDIS CORPORATION,	CIVIL ACTION
Plaintiff	
vs.	
BOSTON SCIENTIFIC CORPORATION,	NO. 98-197 (SLR)
et al.,	
Defendants	

Wilmington, Delaware
Thursday, November 16, 2000
9:45 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Official Court Reporters

1 APPEARANCES (Continued):

CONNOLLY, BOVE, LODGE & HUTZ LLP
BY: PATRICIA SHANK RODOWSKI, ESQ.

MORGAN, LEWIS & BOCKIUS
BY: WILLIAM WALLACE, ESQ.,
D. MICHAEL UNDERHILL, ESQ.,
RICHARD S. MEYER, ESQ.,
MICHAEL V. FRANK, ESQ.,
PELOLOPE M. LISTER, ESQ. and
ERIC J. MAUREA, ESQ.
(Washington, D.C.)

Counsel for Plaintiff/Defendant Medtronic
AVE, Inc., Formerly Arterial Vascular
Engineering, Inc.

BEST AVAILABLE COPY

1 APPEARANCES

ASSTY & GEORGE
BY: STEVEN L. BALICK, ESQ.

PATTERSON, BELKNAP, WEBB & TYLER LLP
BY: GREGORY L. DISKANT, ESQ.,
EUGENE M. GELBERMAN, ESQ.,
WILLIAM F. CAVANAUGH, JR., ESQ. and
MICHAEL J. THOMAS, ESQ.
(New York, New York)

KIRKSON & JOHNSON
BY: ERIC J. MAUREA, ESQ.

Counsel for Plaintiff/Defendant Cordis
Corporation

PROCEEDINGS

(Proceedings commenced in the jury room,
beginning at 9:45 a.m., between the Court and the jurors
only.)

THE COURT: I just wanted to have a discussion
with you. I know I have been pushing you all very hard,
that this is difficult material. And, because I am a
morning person, I try to make my mornings long, because
I have difficulty sometimes focusing on what is happening
in the afternoon.

So I know it's been difficult for you all to
sit as long as I am more used to.

A couple of things. Number one, please feel
to bring in mints or candy, drinks, to help you stay
focused, because that will help. I want you to know that
it is obviously important that if you need a break, if any
of you ever need a break for any reason, if you just -
there is nothing worse than feeling like you are about
ready to lose it and fall on the floor, you need to just
get Betty's attention and we will take a break, because
you are the most important part of this trial and we want
to make sure that we are doing what we can to accommodate

1. "Question: Was there ever a time while you
2 were at JIS when you communicated with either of those
3 gentlemen regularly?
4 "Answer: Yes.
5 "Question: When was that?
6 "Answer: With Dr. Palmaz as Manager of New
7 Products, I worked on peripheral stent designs and traveled
8 frequently to San Antonio to meet with Dr. Palmaz and
9 discuss new stent designs.
10 "Question: Did you ever work with Dr. Schatz?
11 "Answer: Yes. When I was Product Director
12 for Cardiology Systems, I worked very closely with Dr.
13 Schatz in planning the launch of the Palmaz-Schatz stent.
14 "Question: If you could look at Page 5 of Mr.
15 Bonsignore's document CO, which is COR 602330...
16 "The first bullet indicates radiopacity. Is
17 that the same visibility you were talking about some time
18 ago?
19 "Answer: Yes.
20 "Question: In the second sentence -- the
21 PS-153 is a Palmaz-Schatz stent; is that correct?
22 "Answer: Yes.
23 "Question: This paragraph indicates that the
24 AVE stent is more distinct than the Palmaz-Schatz stent.
25 Does that mean it's more visible?

1 "Answer: I would read this sentence to me
2 that it is more visible on a fluoroscopy display.
3 "Question: What does wall thickness mean?
4 "Answer: To me the wire diameter would be
5 analogous to the wall thickness.
6 "Question: What do you mean analogous to the
7 wall thickness?
8 "Answer: AVE is a coil stent, so it does not
9 have wall thickness of a tube. The diameter of the wire
10 would be the determining factor in the visibility under
11 X-ray.
12 "The Videographer: Off the record at 6:08."
13 MR. DISKANT: I would like to introduce Ms.
14 Kelly Abrams (phonetic), who is going to assist, with
15 your Honor's permission.
16 MR. TIMMONS: If your Honor please, ladies
17 and gentlemen of the jury, we are going to introduce
18 testimony from Ms. Scheller regarding her marketing
19 efforts at JIS and Cordis and also that she was not --
20 when she testified about coil stents as you just heard,
21 she was not talking about that term in terms of any
22 patents.
23 I would like to direct your attention to Page
24 8 of Ms. Scheller's May 28, 1999 deposition at Line 3,
25 where she was asked:

1 "What is your current position?
2 "Answer: Vice President of Marketing.
3 "Question: At what company?
4 "Answer: Dave Barry (phonetic)."
5 MR. TIMMONS: Actually, I would like to
6 direct your attention to Page 170 of Ms. Scheller's May 28
7 deposition, Line 22, in which she was asked:
8 "If you look back at your time at JIS, now
9 you were there from 1992 to 1997, what would you say were
10 JIS's greatest challenges in the context of stent and
11 stent delivery system markets?
12 "Answer: With regard to stent and stent
13 delivery markets?
14 "Question: Stent delivery system markets.
15 "Answer: The greatest challenge for JIS was
16 in establishing the market itself, because no market had
17 previously existed.
18 "Question: By establishing the market itself,
19 you mean persuading cardiologists, when the Palmaz-Schatz
20 was first introduced to the market to use the stent?
21 "Answer: Even prior to the launch of the
22 product, it was necessary to work with cardiologists to
23 establish the validity of requiring the stent procedure."
24 MR. TIMMONS: Next I would like to direct
25 your attention to Page 448 of Ms. Sheller's December 20,

1 1999 deposition, at Line 17, where she was asked:
2 "Now, do you remember testifying about what
3 you called coil stents?
4 "Answer: Yes.
5 "Question: And do you remember testifying
6 about what you called slotted tube stents at the prior
7 depositions?
8 "Answer: Yes.
9 "Question: And when you used those terms,
10 coil stent and slotted tube stent, were you using,
11 defining those terms in accordance with how those terms
12 are used in any patent?
13 "Answer: No.
14 "Question: And were you thinking of any patent
15 when you described those terms?
16 "Answer: No. Nothing further."
17 MR. UNDERHILL: Your Honor, AVE calls Dr. Van
18 Breda, please.
19 ---
20 DEFENDANT'S TESTIMONY
21 CONTINUED
22
23 ... ARINA VAN BREDa, having been
24 duly sworn as a witness, was examined
25 and testified as follows ...

1 MR. UNDERHILL: Dr. van Breda is an
2 interventional radiologist who has been treating
3 patients with vascular disease for 20 years. She is a
4 Clinical Professor of Radiology at George Washington
5 University in Washington D.C.

6 Her testimony will primarily focus on the
7 1985/1988 time frame. She will testify, among other
8 things, as to whether the improvement in the '984 patent
9 was obvious in light of the prior art that was then
10 available to one of ordinary skill in the art.

11 DIRECT EXAMINATION

12 BY MR. UNDERHILL:

13 Q. Hello, Dr. Van Breda.

14 A. Hello.

15 Q. I don't want to know any conclusions that you have
16 drawn quite yet. But have you come here today prepared
17 to testify with a reasonable degree of certainty whether
18 Claims 1 and 3 of the '984 patent would have been obvious
19 to one of ordinary skill in the art?

20 A. Yes, I have.

21 MR. UNDERHILL: Could we have the cover page of
22 the '984.

23 BY MR. UNDERHILL:

24 Q. Before we get to that, Dr. Van Breda, I would like
25 to first explore your education and your experiences that

Page 2078

1 qualify you to testify about the obviousness of the claims
2 in the '984 patent.

3 What is your current occupation?

4 A. I am an interventional radiologist at Alexander Reed
5 Hospital in Alexandria Virginia.

6 Q. That is outside of Washington, D.C., isn't it?

7 A. Immediately outside.

8 Q. Do you also hold any faculty positions?

9 A. I am a Clinical Professor of Radiology at the George
10 Washington University Hospital.

11 Q. How long, approximately, have you been affiliated
12 with George Washington University?

13 A. Since I started my practice in 1983 in Alexandria.

14 Q. About 17 years?

15 A. That would be right.

16 Q. Could you summarize your educational background for
17 us, by which you qualify to become an interventional
18 radiologist?

19 A. Well, after an internship in internal medicine and
20 a radiology residency at George Washington University, I
21 did a two-year Fellowship in cardiovascular radiology at
22 Mass. General Hospital in Boston, Massachusetts, that
23 comprised one year of cardiac radiology, and then an
24 additional year of purely vascular radiology.

25 After that I spent an additional year as a

1 staff member in a teaching position at Mass. General
2 Hospital. And from there, in 1983, I moved to Alexandria
3 Hospital.

4 Q. Now, where did you receive your medical degree?

5 A. At Boston University.

6 Q. Since finishing your residency, could you please
7 explain for the jury some of your relevant clinical
8 experiences relating to stents?

9 A. Well, beginning with both my residency then
10 continuing on through my Fellowship, I have had
11 significant experience in the whole field of vascular
12 interventional, of which stents is a part. I have had
13 an interest in new devices that have developed over that
14 period of time, that have been useful for treating
15 vascular problems, stents were one of those techniques.

16 So beginning about the mid-1980's, towards
17 late 1980's, I was involved in both testing stents, parts
18 of clinical trials, including the Palmaz single stent for
19 iliac use, as well as the articulated, joined Palmaz-
20 Schatz-type stent for renal arteries, and I have had
21 experience with all kinds of other stents, self-expanding
22 stents, Z-stents, pretty much every stent that has been
23 available for peripheral use since I started.

24 Q. You mentioned the iliac arteries. Where are the
25 iliac arteries in the human body?

Page 2080

1 A. The iliac arteries are the arteries that supply
2 the main blood flow to the legs. The aorta is the main
3 blood vessel that runs through the abdomen and then it
4 branches into two major branches, one to each leg. Those
5 are the major arteries that supply blood to the legs.

6 Q. Let me put a demonstrative up on the board showing
7 the circulatory system.

8 Can you explain this diagram for us briefly?
9 You don't need to go through all of them.

10 A. Here is the abdominal aorta. This is the
11 continuation aorta. It arises from the heart and continues
12 down from the chest and into the abdomen. It branches off
13 to all of the major organs in the abdomen, and then
14 branches here, as you can see, into both the branch of the
15 right and left leg. Those are the iliac arteries. There
16 are other arteries here where stenting can be performed,
17 the renal arteries, I don't believe they are on this,
18 those would be the arteries to the kidney.

19 Q. I see renal vein. Would the renal arteries be
20 somewhere in that general vicinity?

21 A. Yes, there would be. There is also a celiac artery
22 there that supplies the spleen and the liver. There is
23 also mesenteric artery that supplies the large intestine.

24 Q. Speaking generally, what arteries and other vessels
25 do you typically work in?

Page 2077 - Page 208

1 A. Well, as an interventional radiologist, we basically
2 work in the entire vascular system. So beginning with the
3 carotid arteries, that supply the blood supply to the
4 brain, upper extremities, the arms, arteries in the chest,
5 all over the arteries that supply the organs in the
6 abdomen, then the arteries in the legs going down to the
7 arteries in the calf.

8 Probably the only part of the arterial system
9 that we don't deal with is the coronary arteries, which
10 is largely the purview of the cardiologists. In addition
11 to the arteries, when we say vascular system, we are not
12 talking simply about arteries. We are also talking about
13 veins. And part of my clinical experience with stents
14 has included treating venous narrowings, problems with
15 the veins.

16 Those are the structures here in blue on
17 this diagram. We would have experience with doing stent
18 procedures in the superior vena cava, and inferior vena
19 cava and other veins in the body.

20 Q. You mentioned something about clinical trials and
21 you being involved in clinical trials involving the Palmaz
22 or Palmaz-Schatz stents. Would you please tell us what
23 those clinical trials were?

24 A. Part of the work that was done early on to establish
25 the efficacy, how useful were these devices, the Palmaz

1 interventional procedures. Basically that is a full-time
2 job, teaching young doctors to do these procedures.

3 In addition, I have participated in multiple
4 medical meetings, both in the United States and around
5 the world, educating physicians about the use of stents.
6 At Alexandria Hospital we actually ran a meeting where
7 we would demonstrate the use of stents in a live-case
8 demonstration to show physicians how these procedures
9 were done. And that was particularly, during that time
10 period, a very active part of my interest.

11 Q. In 1987 -- was that when this was, that you were
12 referring to?

13 A. We did it numerous years. That was one year we did
14 that.

15 Q. Have you ever lectured at the RSNA?

16 A. The Radiologic Society of North America is the
17 major educational meeting for radiologists, of which
18 interventional radiology is part. So it is where most of
19 the radiologists in the country would show up. And that
20 year I ran a refresher course, where I talked specifically
21 about new vascular devices, including stents.

22 Q. And I understand you have been a Visiting Professor
23 at a number of medical schools. Would you tell us about
24 that, please?

25 A. I have been an invited lecturer and Visiting

1 stent, in treating iliac artery blockages and narrowings.

2 Q. How about the Palmaz-Schatz stent?

3 A. That was a trial that was geared to look
4 specifically at how well the Palmaz-Schatz type stent
5 could work in the renal arteries, the arteries supplying
6 the kidneys.

7 Q. Have you implanted other types of stents, other
8 than the Palmaz and the Palmaz-Schatz?

9 A. Yes. As I mentioned, I have had experience with
10 pretty much every stent type for peripheral use that has
11 become available.

12 Q. What are some of those stents?

13 A. Well, one stent we use fairly frequently is a self-
14 expanding stent called a wall stent, and subsequent
15 variations or modifications of that. We have used
16 Gianturco stents. We have used the Palmaz stents.

17 And those are the major ones, I would have
18 to say. There are some modifications with various trade
19 names.

20 Q. Have you been involved in the education of students
21 or other doctors throughout the years concerning stents?
22 And I would like you to particularly focus on the time
23 period before 1988.

24 A. Certainly. As Director of the Fellowship Program
25 in Alexandria Hospital, we train Fellows to perform

1 Professor at institutions all over the United States as
2 well as in Europe and Australia, regional here, I have
3 been a Visiting Professor at the University of
4 Pennsylvania, at Johns Hopkins, Thomas Jefferson
5 University.

6 Q. Have you been involved in the course of your career
7 with any specialty organizations that have added to your
8 knowledge of stents?

9 A. I have been very actively involved with the leading
10 organization, I had mentioned before the Radiologic
11 Society of North America represents radiologists, my
12 subspecialty, which is interventional radiology, has its
13 own specialty organization, that is the Society for
14 Cardiovascular and Interventional Radiology. And we have
15 an annual meeting and produce publications. I have been
16 very actively involved with them. Was President of the
17 organization as well as the Chairman of the annual
18 meeting. And that was actually in that same time frame,
19 1988.

20 Q. You were President of a committee or you were
21 President of the entire organization?

22 A. I was President of the entire organization.

23 Q. And when was that?

24 A. That was 1990/91.

25 Q. Have you also been active with the American Heart

1 Association?

2 A. Yes. I have served on the Cardiovascular - the
3 Council for Cardiovascular Radiology of the American
4 Heart Association. I have also been very active with the
5 Radiologic Society of North America. I have also served
6 for the American Board of Radiology, which is the Board
7 that oversees the accreditation of physicians who perform
8 interventional radiology, as well as radiology.

9 Q. Have you written any publications on interventional
10 radiology and vascular disease?

11 A. Yes, I have.

12 Q. Without telling us the details of each one, could
13 you briefly tell us what that is?

14 A. I have written a number of articles, specific to
15 interventional radiology, largely concentrating on
16 vascular radiology, my major areas of interest have been
17 thrombolytic therapy, drugs given to try to dissolve
18 blood clots in arteries and veins. And I have also
19 written a fair amount on new vascular devices, which
20 include, in this time, stents, lasers, things like that.

21 Q. Have you written any books related to vascular
22 disease?

23 A. I co-edited a two-volume work on vascular disease.

24 Q. And, unfortunately, I think I forgot to bring it.
25 Perhaps I will be able to get it at the lunch break.

1 for Cordis, and it was sometime in around that same time
2 frame.

3 Q. So you were invited by Cordis to serve on this
4 advisory panel?

5 A. Yes, I was.

6 Q. Do you have any prior experience with AVE or
7 Medtronic?

8 A. No.

9 Q. Are you being compensated for your time?

10 A. Yes, I am.

11 Q. What is your compensation?

12 A. It's \$450 an hour.

13 Q. Have you ever testified in court before?

14 A. No, I haven't.

15 Q. Have you ever been an expert in a patent case before?

16 A. No.

17 Q. We have heard a lot in this trial about
18 interventional radiologists and interventional
19 cardiologists. What is an interventional cardiologist?

20 A. An interventional cardiologist is a cardiologist
21 who treats diseases of the heart, using an endovascular
22 technique. When we say endovascular, basically that
23 means working from the inside. Instead of opening up the
24 arteries from the outside, like a surgeon would do, you
25 work through the arteries or endovascular. And their work

1 Would you tell us about the two-volume set you edited?

2 A. It was published in 1994. It was really one of
3 the first of its type, to look at vascular disease from
4 not just the perspective of the single specialty, but
5 multiple specialties. I co-edited this with a vascular
6 surgeon. And we had literally over a hundred authors
7 writing chapters on this. And it was a very well-received
8 textbook and was used extensively during that time frame
9 for teaching residents and other physicians about vascular
10 disease.

11 Q. And you were author of chapters in the book as well?

12 A. Yes.

13 Q. Who was your book directed towards?

14 A. It is directed primarily to people interested in
15 the treatment of vascular disease, vascular surgeons,
16 interventional radiologists, interventional cardiologists
17 who also might work in the vascular system outside of
18 coronaries.

19 Q. Have you had any prior experience with Johnson &
20 Johnson before today?

21 A. Well, yes. When our hospital was a site for the
22 Palmaz iliac trial and the Palmaz-Schatz renal trial,
23 that was done for Johnson & Johnson, essentially.

24 Q. And do you have any prior experience with Cordis?

25 A. Yes. I have served on a Physician Advisory Panel

1 is largely limited to the coronary arteries.

2 Q. Could you highlight for us or contrast for us the
3 differing responsibilities for an interventional
4 radiologist and an interventional cardiologist?
5 A. Well, the difference has a lot to do with the
6 diagram that we have already reviewed, which is an
7 interventional cardiologist is largely - not exclusively,
8 but largely limited to working in the coronary arteries.

9 The interventional radiologists works in the
10 entire vascular system, literally from the head down to
11 the feet. And, in addition, we do not do just vascular
12 work. A significant portion of our work is outside of
13 the vascular system, working with the lungs, the trachea,
14 the gastrointestinal system, the biliary system, the
15 kidneys, fallopian tubes, pretty much you name it, and we
16 got a catheter in it.

17 Q. And I understand that you are an interventional
18 radiologist. By the way, that is the same as Dr. Palmaz,
19 isn't it?

20 A. Yes.

21 Q. Do you have experience with cardiovascular
22 applications?

23 A. Well, because of my background and my training,
24 having spent a year as a Fellow in the Cardiac Catheter
25 Laboratory at the Massachusetts General Hospital, what

1 I did was spend a year doing cardiac catheterization.
 2 I continued to be active in cardiac work when I came to
 3 Alexandria Hospital, because it was an area of interest
 4 of mine, and served for a period of time during the years
 5 that you have referred to as the Co-Director of the
 6 Cardiac Catheterization Laboratory at Alexandria Hospital.
 7 We work very closely with our cardiologists.
 8 Q. You mentioned previously, or we saw the diagram here
 9 of the circulatory system. In terms of size and
 10 tortuosity - first what you will, what do mean by
 11 tortuosity, if I am pronouncing that correctly?
 12 A. Basically it means an artery that doesn't go in a
 13 straight line. Arteries that kind of make bends and
 14 curves.
 15 Q. In terms of size and tortuosity, how do the vessels
 16 you work with compare to the coronary arteries?
 17 A. We deal with a much wider range, because we are
 18 dealing with everything from the very largest to the very
 19 smallest. The coronary arteries are among the smallest
 20 arteries that are treated on a regular basis. Tortuosity,
 21 there are parts of the vascular system that we treat that
 22 are very similar to the coronary arteries, in terms of
 23 tortuosity.
 24 Q. I have the '984 patent up here. We are going to
 25 look at Column 5, Lines 25 to 31.

1 While we are getting that, Dr. Van Breda, what,
 2 if anything, does the '984 patent say about whether the
 3 patent is directed only towards stents for the coronary
 4 arteries?
 5 A. Well, as the display here shows - can you tell me
 6 where that is in here?
 7 Q. It would be Plaintiff's 6. We are looking at Column
 8 5, Lines 25 through 31.
 9 A. Okay. Here in the description, it states that this
 10 could be used for various body passageways. So that the
 11 term intraluminal vascular graft encompasses using
 12 expanding along a body passageway. All of the things I
 13 just talked about, areas that we work in, as interventional
 14 radiologists, would be body passageways. So the inside of
 15 a kidney, the inside of a bile duct, the inside of the
 16 esophagus, those are all body passageways.
 17 Q. In the vascular system, I think you have said that
 18 stents are used to treat narrowness. Is that your
 19 testimony?
 20 A. Yes.
 21 Q. Was this the first technique, that is stents, was
 22 stents the first technique to treat narrowings?
 23 A. No, not at all. The first successful technique for
 24 treating narrowings in any part of the body - but let's
 25 limit it specifically here to the vascular system - was

1 angioplasty, was the concept of dilating up an artery.
 2 Stents were basically a modification of that.
 3 Q. We have had testimony here in the courtroom from
 4 Dr. Collins, one of the Cordis' experts, that one of
 5 ordinary skill in the art in the 1984 to 1998 time frame
 6 would have been a physician practicing in the field of
 7 treating occlusive vascular disease, working in
 8 combination with an engineer with a B.S. degree in
 9 mechanical or biomedical engineering or material science
 10 and five years experience in designing medical devices
 11 for implantation in the body.

12 I understand from your testimony you are not
 13 an engineer. If we focus on the first part of that, a
 14 physician practicing in the field of treating occlusive
 15 vascular disease, do you meet that definition?

16 A. Yes, I think so.

17 ---

1
 2 Q. And using Cordis' level of skill of one of ordinary
 3 skill in the art, is it your opinion that Claims 1 and 3
 4 of the '984 patent would have been obvious to one of
 5 ordinary skill in the art?
 6 A. Yes, they would have.
 7 Q. And what did you do to reach your conclusion that
 8 Claims 1 and 3 of the '984 patent would have been obvious
 9 to one of ordinary skill in the art?
 10 A. Okay. I reviewed the material that was available
 11 prior to the date of that application, including prior
 12 patent applications, as well as articles in the medical
 13 literature that were pertinent to the subject.
 14 Q. Okay. And Dr. van Breda, just so we all understand
 15 your qualifications, are you an expert in patent law?
 16 A. No, not at all.
 17 Q. Are you an expert in patent procedure?
 18 A. No.
 19 Q. And before this case, had you read patents before?
 20 A. No.
 21 Q. You're a doctor, is that right?
 22 A. Yes.
 23 Q. Okay. When you say it would have been obvious to
 24 one of ordinary skill in the art, what do you mean by
 25 obvious?

1 A. Well, that someone would have come to the
2 conclusions in the devices that were described in the
3 claims of this particular patent, using the material that
4 we have already referenced and recognizing what the
5 clinical requirements were at the -- during that period
6 of time.
7 Q. And I believe your testimony was that you reviewed
8 these materials from the perspective of one of ordinary
9 skill in the art, correct?
10 A. Correct.
11 Q. Do you consider yourself to be one of ordinary skill
12 in the art?
13 A. Well, without bragging, I think it might be safe to
14 say I'm probably better than ordinary skill in the art,
15 but I've used that as the perspective in making this
16 analysis.
17 Q. Okay. Thank you. Now, you said you considered
18 various articles and patents, and I'd like to go now
19 through some of these references and have you tell the
20 jury how one of ordinary skill in the art would have
21 interpreted those reference as of their publication and
22 filing dates.
23 If we could start by looking at Plaintiff's
24 Exhibit 3, which is the '762 patent...
25 MR. UNDERHILL: If we could also have it on the

1 MR. UNDERHILL: If we could have it side by
2 side...
3 THE WITNESS: Well, the primary difference
4 is that the '762 patent discloses just a single one of the
5 Palmaz stents, a single unit, and the '984 discloses
6 multiple -- I think the terminology is plurality of these,
7 of members connected together.
8 MR. UNDERHILL: Could we please have the pullout
9 for the '984?
10 BY MR. UNDERHILL:
11 Q. And Dr. van Breda, you will recognize that some of
12 the claim terms out of the '984 are also in the '762,
13 specifically, "thin-walled tubular members," "wall surface
14 having a substantially uniform thickness" and "slots formed
15 therein."
16 Are these claim terms here, are these additions
17 to the '984?
18 A. Yes. That's what distinguishes the tube.
19 Q. So we have "connector member," to "flexibly connect
20 adjacent tubular members" and "substantially parallel?"
21 A. Correct.
22 Q. Okay. Dr. Van Breda, based on your analysis of the
23 prior art, do you believe that it would have been obvious
24 to one of ordinary skill in the art to have connected the
25 original slotted tube stent in the '762 patent to come up

1 screen, please...
2 BY MR. UNDERHILL:
3 Q. What is the filing date of the Palmaz '762 patent?
4 A. It says --
5 Q. Would you refresh us?
6 A. -- filed November 3, 1986.
7 Q. And was the '762 patent that we're looking at here,
8 was this filed before the October 4, 1988 filing date of
9 the '984 patent?
10 A. Yes, it was.
11 Q. Okay. So in your review, did you consider the '762
12 patent to be prior art to the 9834 patent?
13 A. Yes, I did.
14 Q. So when you did your obviousness analysis to see if
15 the claims of the '984 were -- would have been obvious,
16 did you assume that the '762 patent was in the body of art
17 that one of ordinary skill in the art would have known?
18 A. Yes, I did.
19 Q. Could you just describe in the most general terms
20 what the '762 patent discloses based on your reading of it?
21 A. Essentially what it discloses is the basic Palmaz
22 stent, a slotted tubular stent. A single member.
23 Q. And what did you understand to be the difference
24 between the slotted tube stent of the '762 patent and
25 the stent which is disclosed in the '984 patent?

1 with the '984 patent?
2 A. Yes, I do believe so.
3 Q. Okay. Why do you believe that, Dr. Van Breda?
4 A. Again, let's just start with kind of what the
5 clinical needs are at this point in time. That we
6 already talked about the fact that the arteries are not
7 often in a straight line, they're curved, and what are
8 you trying to do is treat an artery that is not
9 necessarily in a straight line. In order to do that, you
10 need to be able to go around curves with the device. You
11 can't do that if the device is rigid and stiff. You have
12 to be able to have some flexibility in that system.
13 So if you presume the basic Palmaz stent,
14 which is a rigid stent, and you need to get a rigid stent
15 around bends, what you have to do is figure out a way to
16 get it flexible. And one way to do that is to take
17 segments of a Palmaz stent and connect them up together
18 and use them in that way.
19 Q. And you understand that the patent teaches a
20 flexible connector member?
21 A. Yes.
22 MR. DISKANT: Objection to statements contrary
23 to the Court's claim construction.
24 MR. UNDERHILL: It wasn't intended to be. I
25 don't believe it was.

MR. DISKANT: It was.

MR. UNDERHILL: I believe that is entirely consistent with the testimony the Cordis witness provided.

THE COURT: Go on. The jury will be able to determine whether it is consistent with the claim construction at the end of the day.

BY MR. UNDERHILL:

Q. Let's go back in time, Dr. van Breda. Let's go back to the 1985/1988 time frame and let's have you tell us what the prior art looked like. Besides the Palmaz slotted

tube design -- we're talking about the original one, the '762 -- were any other types of Palmaz stents known to those of ordinary skill in the art during this time period?

A. Yes. Dr. Palmaz had originally described a different type of stent, which was a woven wire mesh stent.

Q. Okay. Would you please take a look at Defendant's Exhibit 1224?

MR. UNDERHILL: Which I move into evidence. It's an article by Dr. Palmaz.

Don't put it up on the screen, please.

MR. DISKANT: No objection.

*** (Defendant's Exhibit No. 1224 was received into evidence.)

MR. UNDERHILL: Put it up on the screen now.

There is no objection by counsel.

Page 2098

BY MR. UNDERHILL:

Q. Dr. Van Breda, what do you consider to be the significant event here? And let's start with the publication date when was it published. I believe it's on the first page.

A. 1985.

Q. Okay. July of 1985?

A. Yes.

Q. And what, in general, do you understand this article to disclose to one of ordinary skill in the art as of 1985?

A. Okay.

Q. And specifically let me direct your attention to Figure 1. This is the figure or a figure out of it.

A. Okay. What this article discloses is the initial device described by Dr. Palmaz, which was the woven wire mesh.

Q. Okay. And back in this time period, would it have been known to one of ordinary skill in the art that the woven wire mesh design was rigid?

A. Well, in the same article, on Page 76, that is something that Dr. Palmaz specifically states.

Q. And would it have been known to one of ordinary skill in the art that the wire mesh --

MR. DISKANT: Your Honor, I'll object to the leading. I think direct questions should be posed.

MR. UNDERHILL: I thought that is what I was doing.

THE COURT: Well, try to rephrase it and we'll see if you do it again.

BY MR. UNDERHILL:

Q. Back in this time, would one of ordinary skill in the art have had an opinion about whether or not the woven wire mesh design stent would work in the coronary arteries?

A. Given that Dr. Palmaz specifically refers to the problem with the inherent lack of flexibility with this device, anyone of ordinary skill in the art would have readily known that this was not going to be a device that was readily amenable for use in the coronary arteries.

Q. During this period of time, would one of ordinary skill in the art have thought about using the stents in tandem?

A. Yes. Again, as I said earlier, the clinical situation would suggest to you that you use -- if you can't use one long rigid stent, use smaller stents, even if they are rigid, and have them connected in some way. And again, Dr. Palmaz specifically states that in the article here, as you can see.

It says:

"The problem is later solved by

using shorter grafts or grafts in tandem."

Q. Okay. And what did you understand the grafts in tandem to refer to?

A. To me, what that means is that you're using more than one graft. And graft here in this particular instance means specifically a stent. Using more than one to treat a given area of disease.

Q. Okay. I'd also like to have you take a look at Defendant's Exhibit 364, please.

MR. UNDERHILL: And I'll submit this into evidence.

MR. DISKANT: No objection.

*** (Defendant's Exhibit No. 364 was received into evidence.)

MR. UNDERHILL: And can we have it on the screen, please?

BY MR. UNDERHILL:

Q. Could you tell us the publication date of this Wallace article?

A. Okay. This is 1986.

MR. UNDERHILL: And actually, this is actually already into evidence.

BY MR. UNDERHILL:

Q. What is the publication date? You said 1986?

A. Yes.

Page 2100

1 Q. And what would this article have disclosed to one of
2 ordinary skill in the art as of 1986?

3 A. Okay. What this, what this article is about is
4 something called a Z-stent, a Gianturco Z-stent. And in
5 this article they basically show two segments, two Z-stents
6 connected together by a connecting bar.

7 Q. Okay. And where are you looking?

8 A. Well, if you look on Page 310, in the figures, it
9 shows.

10 Q. Would that be Figure 2?

11 A. Yes, Figure 2, Figure 3.

12 Q. It's on the next page. Kind of illegible here.

13 Okay. Actually, not as bad as I thought.

14 These are the documents you are talking about?

15 A. Correct.

16 Q. And you referred to this as a connected Z. There
17 has been a fair amount of testimony on this point.

18 Probably don't need to spend a lot of time on this. This
19 is a self-expanding stent; correct?

20 A. Correct.

21 Q. And do we agree that has a zig-zag shape to it?

22 A. Yes.

23 MR. DISKANT: Your Honor, this is all
24 cross-examination. Can we have direct questions, please?

25

1 A. Yes, it is.

2 Q. Is that idea the connector member has to be parallel
3 to the longitudinal axis of the tubular member?

4 MR. DISKANT: Your Honor, objection. This is
5 all leading questions.

6 THE COURT: Yes.

7 MR. UNDERHILL: Okay. Could we go back to
8 the '984 patent, please? And specifically the board.

9 BY MR. UNDERHILL:

10 Q. And we see here the term "substantially parallel."
11 Do you see that, the '984 patent?

12 A. Yes.

13 Q. And is in fact the substantially parallel claim
14 limitation present in the Wallace article that we were
15 just looking at?

16 MR. DISKANT: Your Honor, can the witness be
17 asked what her opinions are instead of Mr. Underhill's?

18 MR. UNDERHILL: Your Honor, I thought I'm
19 doing it as neutrally as I can. If there is another
20 phraseology counsel would prefer, I'm happy to use it.

21 THE COURT: Well, let's go on and I'll try to
22 pay more attention. All right?

23 BY MR. UNDERHILL:

24 Q. Dr. Van Breda, would you please tell us whether the
25 "substantially parallel" limitation of the '984 patent is

1 BY MR. UNDERHILL:

2 Q. How would you characterize the shape, Dr. van Breda?

3 A. This is a zig-zag shape. A Z-stent.

4 Q. And how many connector members are used in this
5 particular article to connect the Z-stent?

6 A. One.

7 Q. And if we go back to Claim 1 of the '984 patent -

8 MR. UNDERHILL: If we could have that put on
9 the screen, please...

10 BY MR. UNDERHILL:

11 Q. How many connector members are required in the Claim
12 1 of the '984 patent?

13 A. One.

14 MR. UNDERHILL: Let's go back to the one we
15 just had up.

16 BY MR. UNDERHILL:

17 Q. If we look at Figure 2, which is what we were looking
18 at, what is the orientation of a connector member shown in
19 the picture?

20 A. Well, it's longitudinal. It's along the longitudinal
21 axis of each of the bodies of the individual stents that
22 are connected together.

23 Q. Okay. Are you talking about the connector member?

24 A. The connector member.

25 Q. And is it parallel to the longitudinal axis?

1 or is not taught in the Wallace article that we were just
2 looking at?

3 A. The Wallace -

4 MR. DISKANT: Objection, leading.

5 THE COURT: I disagree. I think that is the
6 way to direct, and now it's time for the witness's
7 opinion. And I'll allow the question and the answer.

8 THE WITNESS: Okay. I think the Wallace
9 answer demonstrates the connector, teaches a connector
10 that is substantially parallel to the longitudinal axis
11 of the stents.

12 MR. UNDERHILL: And can we have the Court
13 claim chart on substantially parallel?

14 BY MR. UNDERHILL:

15 Q. And if you look please here at the Court
16 interpretation of "substantially parallel"...

17 Is this the definition of "substantially
18 parallel" that you are using in that testimony?

19 A. Yes.

20 Q. Were there other articles that you reviewed that
21 were published on connected Z-stents prior to the filing
22 date of the '984 patent which is October of 1988?

23 A. Yes. There were other articles talking about
24 connected Z-stents prior to that date. There is one by
25 Turanzangavich (phonetic).

1 Q. Targanovich (phonetic)?

2 A. Yes.

3 MR. UNDERHILL: Could you please look at
4 Defendant's Exhibit 359, which is an article by
5 Targanovich. This is already in evidence.

6 May I have that on the screen, please?

7 THE COURT: And perhaps it would be nice if
8 you had the witness point out as opposed to you direct
9 the witness to what she relied on in her opinion.

10 MR. UNDERHILL: Sure.

11 BY MR. UNDERHILL:

12 Q. What would this article have disclosed to one of
13 ordinary skill in the art in 1981?

14 A. Again it discloses the basically Gianturco Z-stent
15 connected by a connecting bar that is parallel,
16 substantially parallel to the longitudinal axis of the
17 stent.

18 Q. And could you tell us where in the article this is
19 disclosed?

20 A. Yes. If you look at this illustration here, B.

21 Q. Okay.

22 A. This is the longitudinal axis of the stent, lies in
23 the artery in this direction and this connector member is
24 parallel to the longitudinal axis.

25 Q. So then, Dr. Van Breda, to make sure we have your

1 the art would have had a reason or motivation to combine

2 the elements about which you have given testimony?

3 A. Yes. As I mentioned earlier, the clinical problem

4 that one is faced with when you are trying to get stents

5 inside of an artery is dealing with arterial segments or

6 vascular segments that are not in a straight line. And

7 when you are dealing with a rigid stent, it's very

8 difficult to get a rigid stent to go around corners. You

9 need to improve or you need to be able to develop some

10 flexibility in order to be able to do that or you are

11 going to be left using very short stents to treat very

12 short segments of disease, and that is often not the case.

13 Very often, you are dealing with long areas of disease.

14 So to treat long areas of disease, to be able to treat

15 that, you know, with one application at one setting, it

16 would make sense to use shorter segments, connect them up

17 together using a single connecting bar.

18 Q. And do you have an opinion as to whether one of

19 ordinary skill in the art would have seen any difficulties

20 with using unconnected shorter stents in tandem

21 A. Well, if you are going to use unconnected shorter

22 stents in tandem, you basically have one of two choices:

23 You can either put one after another after another. And

24 that is -- again is one of the basically principles of

25 doing any kind of vascular intervention: You don't want

1 testimony, do you have an opinion as to whether the prior
2 art during this time period disclosed the unconnected
3 slotted tube stent shown in the '984 patent?

4 A. Yes, it did.

5 Q. And do you have an opinion as to whether the prior
6 art disclosed the use of multiple stents to treat
7 elongated lesions in curved arteries?

8 A. Yes, it did.

9 Q. And do you have an opinion as to whether the prior
10 art disclosed the use of a connector member?

11 A. Yes, it did.

12 Q. And do you have an opinion as to whether the prior
13 art also disclosed the use of one and only one connector
14 member?

15 A. Yes, it did.

16 Q. And did the prior art, in your opinion, also disclose
17 a connector member in a substantially parallel relationship
18 with the stents that it connects?

19 A. Yes, it does.

20 MR. DISKANT: Objection, your Honor. This is
21 a litany of leading questions.

22 THE COURT: You may proceed.

23 BY MR. UNDERHILL:

24 Q. Dr. Van Breda, do you have an opinion, one way or
25 the other, as to whether or not one of ordinary skill in

1 to go back across the diseased area multiple times. The
2 more you do the procedure, the greater the likelihood of
3 risk, so you try to minimize the number of times you are
4 doing something to an artery. So that is not a great
5 option.

6 Another option would be theoretically is to
7 take several stents and try to put them in together at the
8 same time, but not connected together. And that brings in
9 its own clinical problems, which is you're always, whenever
10 you are putting a stent inside of a part of the body, there
11 is always a potential for it to move and not end up exactly
12 where you want it to. And if you are going to be doing
13 multiple ones, particularly at the same time, particularly
14 if not connected together, you run a real risk of them
15 ending up not where you want.

16 Neither are as good an option as to take
17 shorter segments, connect them together and apply them at
18 the same time.

19 Q. Now, Dr. van Breda, if I could direct you to
20 Defendant's Exhibit 461, which is a Palmaz article...

21 Dr. van Breda, do you recognize this document?

22 A. Yes.

23 MR. UNDERHILL: I'll offer it into evidence.

24 MR. DISKANT: No objection.

25 *** (Defendant's Exhibit No. 461 was received

1 into evidence.)

2 BY MR. UNDERHILL:

3 Q. What is the publication date of this article?

4 A. 1986.

5 Q. What does this article generally disclose?

6 A. This article also talks about the original Palmaz
7 design of a woven wire mesh.

8 Q. Okay.

9 MR. UNDERHILL: I'm being handed a note. I
10 thought I done it. I move Exhibit 461 into evidence. I
11 understand there is no objection.

12 BY MR. UNDERHILL:

13 Q. And this is the woven wire mesh design; is that
14 right?

15 A. Yes.

16 Q. And would one of ordinary skill in the art have
17 known of the woven wire mesh design during this time period?

18 A. Yes, because it was an earlier article, the 1985
19 article we talked about.

20 Q. Okay. And, in your opinion, would one of ordinary
21 skill in the art have had a preference as to which type
22 of Palmaz stent would work best in a connected environment?

23 A. Well, in this article, Dr. Palmaz in the last page,
24 Page 204, talks about the reasons why he moved from the
25 woven wire mesh to the stainless steel, the slotted tube

1 where you have to go through lots of turns and curves in
2 a artery. So there still is an inherent rigidity to
3 this stent, to the slotted tube design that is not
4 addressed at all here.

5 Q. Dr. van Breda, could you please take a look at
6 Defendant's Exhibit 3301?

7 Do you recognize as being an article by Dr.
8 Russo?

9 A. Yes.

10 MR. UNDERHILL: Offer it into evidence, your
11 Honor.

12 MR. DISKANT: No objection.

13 *** (Defendant's Exhibit No. 3301 was received
14 into evidence.)

15 BY MR. UNDERHILL:

16 Q. And, in general, Dr. Van Breda, what would this
17 article, Defendant's Exhibit 3301, have disclosed to one
18 of ordinary skill in the art at the time of the
19 publication date, which I believe on the covers says 1987?

20 A. Yes, it says 1987. Well, this is just, you know,
21 further evidence of what I already said, which is that it
22 was obvious there was still rigidity problem with the
23 Palmaz slotted tube design. There is a statement in here
24 specific to that. And it's on Page 159, second column.

25 MR. UNDERHILL: Can we have that pulled out

1 design. And that's in the last paragraph where he talks
2 about solving some of the problems of the woven wire mesh
3 by using instead the lathe design, obtained by
4 electromechanical etching of thin-walled stainless steel
5 tubing.

6 So given that information, his preference
7 would be, and someone of ordinary skill in the art would
8 look at this would say if you are going to be connecting
9 segments together, the best one to use would be this one.

10 Q. And "this one" is which one?

11 A. The stainless steel, the slotted tube design.

12 Q. Now, this provision that you pointed out mentions
13 the slotted tube design solves some of the rigidity
14 problems of the woven wire mesh design.

15 If that is true, if, in fact, some of the
16 rigidity problems of the woven wire mesh design were
17 solved, do you have an opinion as to whether there would
18 be any need to use shorter slotted tube designs in tandem
19 as you have suggested?

20 A. Well, yes. The reason is that may have dealt with
21 some of the rigidity problems but it didn't deal with all
22 of them. This is still -- the slotted tube design is
23 still a very rigid stent. And there is only certain
24 length of it that you are going to be able to use and be
25 able to deliver through a catheter in a vascular system

1 please?

2 BY MR. UNDERHILL:

3 Q. Is this what you were referring to, Dr. Van Breda?

4 A. Yes.

5 Q. It says:

6 "Recently Palmaz showed the advantage
7 of a stent which is placed on an angioplasty
8 probe with a balloon. When the balloon is
9 inflated, it releases a stent into the lumen."

10 And then the footnote says:

11 "Although this principle is attractive,
12 it shows an inflexibility problem, which makes
13 difficult a selective catheterization."

14 Did I read that correctly?

15 A. Yes, it's translated.

16 Q. Okay.

17 A. Not fallaciously. As I said, what this is saying
18 there is still a rigidity problem with the Palmaz design.

19 Q. If you could look at another article by Dr. Russo,
20 please, at Defendant's Exhibit 3303...

21 MR. UNDERHILL: Offer this document into
22 evidence, your Honor.

23 MR. DISKANT: No objection.

24 *** (Defendant's Exhibit No. 3303 was received
25 into evidence.)

1 BY MR. UNDERHILL:

2 Q. I'd like to direct your attention, please, to the
3 passage on Page 13, pullout on the board.

4 A. Okay.

5 Q. It states:

6 "Recently Palmaz, et al. have
7 reported on the use of an expandable
8 device designed on the basis of the
9 expansion metal principle. Although
10 the principle is quite attractive, the
11 relative rigidity of the device suggests
12 that selective catheterization and
13 stenting tight bends or long curves
14 might be difficult."

15 What do you believe? Do you have an opinion
16 as to what that would have taught to one of ordinary skill
17 in the art?

18 A. Yes. It confirms the opinion I gave earlier, which
19 is that the basic Palmaz, the slotted tube design still is
20 a rigid device and there is a real problem with getting a
21 rigid device through any kind of tortured twists or bends,
22 particularly where you are trying to treat a disease of
23 any length. You can get a fairly rigid device around
24 curves if it's relatively short but, if you can imagine,
25 the longer that gets, the more rigidity, the more difficult

1 Q. What would one of ordinary skill in the art have
2 thought about using unconnected stents in tandem?
3 A. Well, as I explained, there are -- there is some
4 real serious clinical concerns if you are trying to use
5 unconnected stents in tandem. It either means you got to
6 go back through an area of disease multiple times in order
7 to get the stent delivered or you are going to try to put
8 these in at the same time, but not connected, in which
9 case I would be very concerned about potential chaos of
10 having these end up not being positioned where you want
11 them.

12 Q. And do you have an opinion as to whether or not one
13 of ordinary skill in the art would have known about these
14 problems?

15 A. I think this is basically principles of
16 interventional angiographic techniques. This is one of
17 the things you learn when you start to work in the
18 arteries. Part of it is common sense. If you are going
19 to be putting two things in, rather than putting them in
20 separately or putting them in at the same time and not
21 being able to control where they end up, neither of those
22 are an optimal solution as being able to put them in at
23 the same time and still control where they end up.

24 Q. Do you have an opinion as to whether one of
25 ordinary skill in the art would have known about the

1 it is going to be to get around curves.

2 Q. You testified there would have been a suggestion to
3 use the rigid slotted tube designs in tandem. What is the
4 basis for your opinion?

5 A. Well, there is Dr. Palmaz's statement that one way
6 to get around problems of the rigidity of the device, if
7 you are trying to treat longer segments of the disease to
8 use stents in tandem, plus again, if you can't use a
9 longer stent, you can use a shorter stent, but if you are
10 going to try to treat long areas of disease, then you have
11 to use multiple of these shorter stents.

12 Q. You referred to Dr. Palmaz's statement. Are you
13 referring to the 1984/5 Radiology article?

14 A. Yes.

15 MR. UNDERHILL: Can we go back to Defendant's
16 Exhibit 1224, please?

17 BY MR. UNDERHILL:

18 Q. Could you find, Dr. Van Breda, 1224 the passage you
19 are referring to?

20 A. Okay. Page 76, first column, last paragraph.

21 Q. Can we have that on the screen, please.

22 A. And in there it says the problem basically being the
23 lack of flexibility and trying to treat in case of curved
24 arteries requires the use of short grafts. And this can
25 be done using short grafts in tandem.

1 potential for migration of the Palmaz slotted tube design?

2 A. Again, I think anyone of ordinary skill in the art,
3 when you are talking about placing a permanently
4 implantable foreign body into a body part, particularly
5 one where there is motion because of the flowing of blood
6 and just respiratory and cardiac motion, there is a
7 concern for potentially having this thing end up not
8 exactly where you want it.

9 So, yes, this is an inherent problem when you
10 are dealing with vascular intervention.

11 Q. Could you please look at Defendant's Exhibit 84,
12 which is also a Palmaz article?

13 MR. UNDERHILL: I offer it into evidence.

14 MR. DISKANT: No objection.

15 *** (Defendant's Exhibit No. 84 was received into
16 evidence.)

17 BY MR. UNDERHILL:

18 Q. What would this have taught to one of ordinary skill
19 in the art?

20 A. This is an article about the use of the single
21 slotted tube design for the treatment of renal artery,
22 kidney artery lesions in an animal model. And it
23 specifically addresses the need to, because you are
24 going around, where the kidney artery often is narrowed,
25 it's right at a bend. I mean it's a 90-degree or better

1 . bend.

2 And it states on Page 707, last column, next
3 or the last full paragraph that:

4 "Stents for renal artery ostial
5 lesions will have to be longer to give
6 a larger stabilizing surface."

7 In order to have this thing stay where you
8 want it, you need to have a longer stent to have it affixed
9 there.

10 MR. UNDERHILL: Offer this into evidence your

11 Honor.

12 MR. DISKANT: No objection.

13 BY MR. UNDERHILL:

14 Q. And do you have an opinion as to whether one of
15 ordinary skill in the art would have understood connecting
16 the stents would appreciate the concerns you identified?

17 A. Again, because of all the stuff we have gone through
18 already, because it's hard to put in a longer stent
19 particularly, when you are trying to make a 90-degree or
20 better angle, it's rigid and it just doesn't want to make
21 that bend.

22 Because of all the evidence we've talked about
23 already, yes, to someone of ordinary skill in the art, it
24 would have made sense to use shorter stent segments and
25 connect them together to get around a bend like that.

1 Q. Is the connector member in the Gianturco Z-stent, is
2 that a flexible connector member?

3 A. Yes.

4 Q. And, hypothetically, if there were testimony from a
5 Cordis expert that that was a rigid connector member,
6 would you agree or disagree with that?

7 A. I would disagree with that.

8 Q. And, hypothetically, if there were testimony that it
9 has to be a rigid connector member, because the connected
10 Z-stent has to be pushed out of the sheath into the human
11 body, would that affect your testimony?

12 A. Well, that's not the case, for one thing. It's not
13 a rigid connector. But even if it were, it really wouldn't
14 matter. I mean, the concept we are getting at here is a
15 connector for whatever purpose. This particular purpose
16 that we are talking about, the clinical need we are trying
17 to solve is how do you deal with a rigid stent where you
18 need a flexible element.

19 And the connector member would allow you to
20 solve that. It would have to be a flexible connector at
21 that point. But, you know, whether or not the Z-stent has
22 got a rigid connector or not - it doesn't but, if it did,
23 it still wouldn't matter. You have the concept of a
24 connector. You see a clinical need for a connector and
25 it would solve it.

1

2 Q. Do you have an opinion as to whether or not one of
3 ordinary skill in the art would have thought it desirable
4 to maintain the spacing between the stents?
5 A. Clearly, this gets back to what I was talking about
6 before, which is that, if you are going to be putting in
7 more than one stent segment, what you want to do is have
8 them end up kind of in a relationship to each other, not
9 too close, or too much overlap, although sometimes we do do
10 that intentionally, or so far apart, or off-angles to each
11 other that it doesn't really treat the part of the diseased
12 artery that your trying to treat.

13 So, yes, someone of ordinary skill in the art
14 would have been aware of this concern.

15 Q. And would one of ordinary skill in the art have been
16 aware that a connector member could play a role in
17 satisfying that concern?

18 A. I think that's pretty obvious, in kind of a common-
19 sense observation, if you are trying to get two things in
20 and you want to have them maintain a relationship together,
21 you got to connect them.

22 Q. Were there connected stents in the prior art during
23 this time period?

24 A. We talked about the Gianturco Z-stents. Those are
25 connected.

1 Q. Is the connected Z-stent pushed out of a sheath?

2 A. Yes.

3 Q. Does the connector member play a role in pushing the
4 connector Z-stent out of a sheath?

5 A. No. The Z-stent, when it is in its sheath being
6 pushed out, it's a very bulky device. It fills most of
7 the inside of that sheath. And if you have got two of
8 them stuck together or two being put in at the same time,
9 the pusher is going to - you know, the rear one that is
10 being pushed, the crown of that is going to abut directly
11 on the crown of the one in front and they will push out
12 together. There is just not enough room in that sheath
13 for them to telescope one within the other. You don't
14 need the connector for a pusher at all.

15 Q. Would one of ordinary skill in the art who set out
16 to design a balloon expandable stent look at or ignore
17 teachings contained in articles relating to self-expanding
18 stents?

19 A. No. Clearly, anyone of ordinary skill in the art,
20 anyone with a shred of common sense who is trying to design
21 a stent is going to look at all of the available stents.
22 This is the same basic clinical problem that we are talking
23 about. If you went to national meetings, if you read the
24 medical literature, when people talked about stents, they
25 talked about them as category stents. They didn't

1 subcategorize them, balloon expandable or self-expanding.
2 These were all considered part and parcel of
3 the same basic technology, different ways to solve a
4 problem.

5 Q. Dr. van Breda, could you please take a look at
6 Defendant's Exhibit 134? This is an article by Duprat
7 (phonetic) and Gianturco. I offer it into evidence.

8 MR. DISKANT: No objection.

9 *** (Defendant's Exhibit No. 134 as received into
10 evidence.)

11 BY MR. UNDERHILL:

12 Q. If I could direct your attention to Page 277...

13 What do you believe this article would have
14 taught to one of ordinary skill in the art?

15 A. Well, what it says is that, again, re-emphasizes the
16 fact that there is a lack of longitudinal flexibility in
17 the original design by Palmaz. This is a balloon
18 expandable stent, trying to overcome some of the
19 flexibility issues that we have been talking about.

20 Q. What was the solution that is referenced in this
21 particular article as to the problem of longitudinal
22 flexibility that you have referred to?

23 A. Okay. What they have done is gone to a balloon
24 expandable, a completely different design, rather than
25 the -- either the Palmaz -- this is more of a spiral-type

1 will ask it a different way.

2 BY MR. UNDERHILL:

3 Q. Does this article have any teaching with respect to
4 whether or not the connected Z-stent is sufficiently
5 flexible to travel through small and tortuous arteries?

6 A. No, it really doesn't talk about connected Z-stents
7 at all.

8 Q. I believe I misspoke. I said connected Z-stent. I
9 meant to say Z-stents. Does the article teach anything on
10 that?

11 A. Well, it talks about the difficulty, they do refer to
12 using the self-expandable Z-stents in arteries, and that
13 they can be used in arteries that are smaller than 5
14 millimeters.

15 Q. Would one of ordinary skill in the art have had an
16 understanding as to whether or not the Z-stent was flexible
17 to travel through small and tortuous arteries?

18 A. The Z-stent itself is a very bulky device, and it is
19 not well suited to use in small and tortuous arteries.
20 When you are talking about very small arteries, trying to
21 get a Z-stent, which is a very bulky design, and it's got
22 a delivery sheath that is very bulky, trying to get that
23 into fairly small arteries, it is a real limitation of
24 that particular system.

25 Q. Let's look at the Claim 1 of the '984, please.

1 stent rather than either the zig-zag or the slotted tube
2 design of Palmaz.

3 Q. And the authors of this article are at M.D. Anderson.
4 That is where a lot of work was done with the connective
5 Z-stents?

6 A. Correct.

7 Q. Does this article, in your opinion, teach away from
8 the use of flexible connectors to connect the Palmaz
9 slotted tube design?

10 A. No. I don't think it addresses it one way or the
11 other. Just because people who have been working with
12 Z-stents who had also gone to using a connector between
13 Z-stents are also working on a balloon expandable flexible
14 stent, that just proves a point that I made earlier, that
15 people were looking to solve these problems, you know,
16 using whatever technology seemed to offer, you know, the
17 best solution for a given situation. So there was a lot
18 of cross-fertilization.

19 Q. Your testimony, I believe, was that one of ordinary
20 skill in the art would have understood the Z-stents to
21 lack the necessary flexibility to travel through small and
22 tortuous arteries; is that correct?

23 MR. DISKANT: Objection, your Honor.

24 MR. UNDERHILL: I believe it is a further
25 statement. I am trying to move it along, your Honor. I

1 Specifically, if I could direct your attention to the
2 reference to coplanar...

3 It says:

4 "The connector member being disposed
5 in a substantially parallel relationship
6 with respect to the longitudinal axis of
7 the tubular members and coplanar with each
8 tubular member."

9 Would one of ordinary skill in the art, in
10 your opinion, have understood there to be a teaching on
11 the coplanar limitation?

12 A. Well, if you assume as prior art the basic Palmaz
13 slotted tube stent, basically, etching it out of a hollow
14 cylinder, and if you are going to, as Dr. Palmaz' articles
15 have pointed out, that this is preferential over the woven
16 wire design that he described, if you are going to start
17 with that as a given, and you are going to talk about
18 making a connecting member, then the most obvious way to do
19 that would be to use that same etching process that cuts
20 away material from that hollow cylinder and just makes a
21 connecting member part and parcel of the final product.

22 So as a result, it would be coplanar, because
23 it's using the same material, in the same plane, as each
24 of the individual stent segments.

25 Q. So do you have an opinion as to whether or not one

1 of ordinary skill in the art would have understood the
2 coplanar limitation to have been taught in the prior art?
3 A. Yes.

4 MR. UNDERHILL: Can I please have the '417
5 patent, which is Plaintiff's 5?

6 BY MR. UNDERHILL:

7 Q. That is Exhibit 3910 in your binder, Defendants'
8 Exhibit.

9 Was the '417 patent, which has a date up here
10 of April 7, 1992 and a filing date of March 28, 1988, did
11 this play a role in your -- was this necessary to your
12 analysis on the opinion that you have offered that the
13 claims of the '984 patent were obvious?

14 A. No. I think all the evidence that we have talked
15 about up until now, you know, makes it perfectly obvious.
16 This is not necessary to that at all.

17 Q. Even though it is not necessary, did you look at this
18 patent as part of your analysis?

19 A. Yes, I did.

20 Q. Let's assume for the sake of the next questions that
21 this is prior art. Would this document affect your
22 obviousness analysis with respect to Claim 1 of the '984
23 patent? In other words, would you change your analysis at
24 all?

25 A. No. It wouldn't. It does demonstrate connecting two

1 art, if what you are trying to get at is the issue of
2 flexibility, if you have got something that you need to
3 connect together, but you want to keep it flexible, the
4 fewer the number of connectors, the more flexible it's
5 going to be. If you have this thing connected,
6 circumferentially all around the face of the dial, it is not
7 going to have that same ability to flex in multiple
8 directions. So fewer is better in this instance.

9 MR. DISKANT: I think he is getting into the
10 claims.

11 THE COURT: I think we are getting into the
12 claims of the '984.

13 MR. DISKANT: I am sorry. I misheard the
14 question. I apologize.

15 BY MR. UNDERHILL:

16 Q. Doctor van Breda, I would like to focus your
17 attention here on the angularly offset concept, which is
18 right here. I think there has been testimony before, if
19 Mr. Diskant will permit me to say it, that this refers to
20 the fact that the connector member here and the connector
21 member here are --

22 MR. DISKANT: Why doesn't he ask the witness
23 what she understands?

24 BY MR. UNDERHILL:

25 Q. What do you understand the angularly offset concept

1 or more parts of a Palmaz stent, two individual Palmaz
2 stents together. It shows it with a connecting member that
3 would be coplanar.

4 Q. Could I direct your attention, please, to Column 4,
5 Lines 8 through 11?

6 A. Okay.

7 Q. Do you have that?

8 A. Yes.

9 Q. There is a statement here at Line 8:

10 "A further feature of the present
11 invention is that at least one connector
12 member may be disposed in a non-parallel
13 relationship with respect to the longitudinal
14 axis of the tubular members."

15 Do you see that?

16 A. Yes.

17 Q. What would this portion of the '417 patent have
18 taught, if anything, to one of ordinary skill in the art,
19 about how many connector members are being taught?

20 A. Well, it says you can have just one. It says you
21 can have more, but it says you can have just one.

22 Q. And would one of ordinary skill in the art have any
23 understanding as to whether or not having a smaller number
24 of connector members would have affected flexibility?

25 A. To me, and I think to one of ordinary skill in the

1 to be as described here?

2 A. I think the easiest way for me to describe it is if
3 you take a stent and you are kind of looking down the barrel,
4 what you want to do is have these connecting members not all
5 at 12:00 and 3:00 all in a line where it would form kind of
6 a seam or a spine, but you would want to have a connector
7 at 12:00, a connector at 3:00, a connector at 6:00. Have
8 them spaced as you go down the different stent segments,
9 so the position of each of the connectors between each two
10 segments is going to be at a different position around the
11 dial.

12 That's my understanding.

13 Q. Do you have an opinion as to whether or not that
14 would have been the understanding of one of ordinary skill
15 in the art?

16 A. Yes. I think that's pretty readily apparent from
17 the illustration.

18 Q. And if we were looking at the prior art before the
19 illustration of the '984 patent, were there any teachings
20 in the art about the angularly offset concept that you
21 described?

22 A. Well, there was Dr. Wiktor's patent, which refers
23 specifically to this.

24 Q. Let's look at Defendant's Exhibit 3961, which is
25 already in evidence.

Specifically, did you consider this Wiktor patent in your analysis in reaching your conclusion that Claim 3 of the '984 patent was obvious in light of the prior art?

A. Yes, I did.

Q. What is the filing date of Wiktor?

A. January 1987.

Q. The filing date, it looks like July?

A. It's not a very good copy. It's July.

Q. Could you please take a look at Claim 10 of the Wiktor patent, which is in Column 6, and explain how dr. Wiktor defines his invention?

A. Basically, what he is talking about is having a device that has multiple, a plurality of stent segments connected together.

Q. Okay. And, in fact, by looking at the drawing here, looking at anything in the patent, is there a teaching about the angularly offset function that you have described?

A. I am sorry. You said looking -

Q. Looking at anything you want in the patent, is there any teaching here about the angularly offset concept that you testified about that is in Claim 3 of the '984 patent?

A. Yes. In Column 3.

Q. Which lines?

A. Between 30 and 45.

MR. UNDERHILL: Can we pull up 34 to 44, please?

BY MR. UNDERHILL:

Q. Specifically, what does this language that you're referring to teach?

A. Here, it's called nonalignment of those loops. It's Loop 6 in the diagram, which is what is functioning as a connecting member here. It says that to have them, nonalignment of the loops permits a more uniform flexing of the stent during deployment to follow the natural bends within the cardiovascular system.

Q. So, you are talking specifically in the Wiktor patent, it says the nonalignment of Loop 6?

A. Right.

Q. If you look up here to Loop 6, one of them is there, one of them is there, one of them is there, one of them is there. Do you have an opinion as to whether that relates to the language in any way?

A. Yes, it does. It is demonstrating exactly what it is talking about, which is that you don't want all of those, you know, connectors lined up so they are all in a row at the same position around the circumference. You want them kind of skewed as you go down the stent segments, you want them to kind of spiral around.

Q. And do you believe that one of ordinary skill in

the art would have understood the angularly offset concept from the Wiktor patent?

A. Yes, I think it was pretty clear.

Q. In concluding that Claims 1 and 3 of the '984 patent were obvious in light of what was in the prior art, did you also take into consideration arguments made by Cordis that stents solved a long-felt need and their commercial success was met with skepticism?

A. Yes, I considered that.

Q. Did you also take into consideration Cordis' position that others failed to solve the problems of balloon angioplasty and there were incentives to find a solution to the problem?

A. I took that into account.

Q. I want you to assume for a moment that Cordis' arguments are correct, that all these arguments are correct. Does that affect your conclusion that Claims 1 and 3 of the '984 patent would have been obvious?

A. Those arguments don't affect it one way or the other. I think all of the points we have discussed so far would have made this a very natural and obvious, common-sense kind of thing to derive, without having to get involved with any of those secondary considerations.

Q. Let's also look at some of the arguments that Cordis has been making here. In his opening remarks to the jury

in this case, Mr. Diskant said that the problem that the stent is intended to solve and does solve is the problem of coronary heart disease. Is Mr. Diskant's statement that stents solve the problem of coronary heart disease accurate?

A. No. I think that's not at all accurate. It would be wonderful if we had a cure for heart disease. But, unfortunately, this isn't it.

Q. What do you believe is the big advance, if there is one, in the interventional treatment of heart disease?

A. There would be no interventional cardiology, and probably very limited interventional vascular radiology if it weren't for angioplasty. Angioplasty was really the breakthrough. That is kind of what allowed endovascular treatment of vascular problems, once you had a way of kind of getting to expand an area of narrowing with a balloon, that was really where things got started.

Q. Was balloon angioplasty the be-all and end-all?

A. No. Fortunately, the nice thing about the medical field is we do make progress on a fairly regular basis. Angioplasty was a breakthrough because, for the first time, you had something that wasn't surgery, or simply saying to the patient, you know, take two aspirin, hope you feel better in the morning.

You had a way of treating heart disease that

1. avoided all of the problems with either a pure medical or
 2 pure surgical approach. But it had problems. I mean,
 3 they were fairly and are fairly well recognized.
 4 Q. What did stents add to the mix?
 5 A. What stents did, and it was a very useful adjunct,
 6 is a very useful adjunct to angioplasty, it allows you to
 7 treat arteries that you might not otherwise be able to
 8 treat successfully. It reduces some of the acute
 9 complications of angioplasty, arteries that want to close
 10 right back down immediately after you have used a balloon
 11 in them.
 12 It allows you to treat other complications,
 13 like something called the dissection, where the artery
 14 wall starts to separate a little bit, you can tack them
 15 down with stents. It probably helps to a degree of
 16 reducing the rate of restenosis, the reclosure of the
 17 arteries after an angioplasty has been performed.
 18 Q. Did stents solve the problems associated with
 19 angioplasty?
 20 A. No.
 21 Q. Were others working on -- that is, other than people
 22 working on stent designs -- were others working on ideas
 23 that could potentially alleviate some of the problems
 24 associated with vascular disease?
 25 A. Yes. And it's an area that continues to be going

- 1 full-throttle. One of the most important advances was
 2 pharmacologic, manipulations, having a better
 3 understanding of what makes blood clot and how to break
 4 up clots whether they occur. There were also other
 5 mechanical devices that are being evaluated for the
 6 treatment of arterial blockages, like an atherectomy
 7 device where you actually scoop out areas of plaque or
 8 lasers to blast through plaques.
 9 Q. When you refer to pharmacological advances, would
 10 that be medicines?
 11 A. Yes.
 12 Q. And do the medicines and the mechanical devices that
 13 you have described, do they have clinical utility?
 14 A. The pharmacological advances, absolutely, they
 15 probably significantly improve the outcomes both of
 16 angioplasty and stents over the last decade. Some of the
 17 other devices have had relatively smaller role. They
 18 still have some use, but it's small.
 19 Q. And are these mechanical devices still used today?
 20 A. Yes.
 21 Q. Were these other approaches as successful as stents,
 22 the mechanical devices?
 23 A. The mechanical devices, no, I think stents were
 24 clearly more successful than the atherectomies and lasers.
 25 Q. When did you first become aware of stents?

- 1 A. It was probably in the mid-1980's.
 2 Q. There has been some statements, I believe, by Mr.
 3 Diskant about skepticism concerning stents. Could you
 4 please describe for us the general attitude among
 5 interventional radiologists and cardiologists in, let's
 6 say, the 1987 to 1994 time period towards stents?
 7 Now, I have moved time periods on you. I
 8 think we were talking about what one of ordinary skill in
 9 the art would have known, you were talking about pre-1988.
 10 Now I am asking you to look at the 1987 to 1994 time frame.
 11 A. Okay. I think it would be fair to characterize the
 12 interest in it on the part of interventional cardiologists
 13 and interventional radiologists of one of great interest,
 14 and very close, this was a field that was developing
 15 fairly rapidly, and there was very close attention being
 16 paid to the advances that were coming out. There was
 17 considerable enthusiasm.
 18 Q. Were people other than Dr. Schatz working on stents
 19 in the mid-to late 1980's?
 20 A. Certainly.
 21 Q. Could you tell us who some of those others were?
 22 A. Well, the entire Gianturco group. There are the
 23 people who worked with Dr. Doddard (phonetic), who was
 24 actually the first person to describe using stents in the
 25 vascular system back in the 1960s already. And then

- 1 people who worked with him continued to work on varying
 2 modifications of his original device.
 3 There were a bunch of stents that were
 4 developed primarily in Europe. The Medivent or Wall stent,
 5 which is a self-expanding stent. Doctor Strecher, working
 6 in Europe, came up with a stent. There are a whole host
 7 of them. Lots of people.
 8 Q. Was Dr. Wiktor one of these individuals?
 9 A. Yes.
 10 Q. Were some of these stents commercialized and became
 11 commercially available?
 12 A. Absolutely, yes.
 13 Q. What are some of the other stents in this time
 14 period that you were aware of?
 15 A. That became commercially available, you mean?
 16 Q. Yes.
 17 A. The Gianturco stent was commercially available, the
 18 Wall stent was widely -- was available initially in Europe
 19 and then became available in the United States. Dr.
 20 Strecher's stent was used for clinical trials. Dr.
 21 Wiktor's stent was used.
 22 Q. Were these other stents successful?
 23 A. To varying degrees, yes.
 24 Q. Do you quarrel with Cordis' position that the
 25 Palmaz-Schatz connected stent design was also successful?

1 A. I don't argue with that.
 2 Q. You mentioned previously that you used the
 3 Palmaz-Schatz stent in renal arteries. What was your
 4 experience with that?
 5 A. We were looking specifically at treating blockages,
 6 just the first part of the kidney artery, the renal artery
 7 as it comes off the aorta. Our experience with it was it
 8 had some role, but there were still some technical problems
 9 with it that led to it not being wholeheartedly embraced or
 10 successful.

11 MR. UNDERHILL: Can we look at the cover of the
 12 '984 patent, please?

13 THE COURT: Mr. Underhill, we are going to take
 14 our luncheon break at 1:00. So whenever it's convenient, in
 15 terms of a stopping point.

16 MR. UNDERHILL: I think I can do it before
 17 1:00, or 1:03. You want to break at 1:00, that is fine,
 18 too.

19 BY MR. UNDERHILL:

20 Q. Could you take a look at the cover of the '984? Do
 21 you know if the design shown on this cover, specifically
 22 I am talking the three-segment stent, do you know if this
 23 design was ever successful?

24 A. I don't believe that this was ever developed or
 25 available commercially. I have never seen one, even for

1 an investigational study. I don't think a three-segment
 2 stent was ever manufactured or used clinically.

3 Q. Is this specific, the three-segment extent, is this
 4 the subject of either of the claims in the '984 patent
 5 that we have been talking about?

6 A. Well, it's Claim 3.

7 Q. And is that because you can't have an angularly
 8 offset feature unless you have at least three?

9 A. Correct.

10 Q. If we focus now on just the Palmaz-Schatz stent with
 11 two slotted tubes, the two, forget about the third, first
 12 of all, was that ever commercialized?

13 A. Yes, clearly, that is the stent that was used and
 14 is available nowadays for both renal and coronary use.

15 Q. What do you attribute its success to?

16 A. I think that, particularly where it has found its
 17 greatest success would have to be in the coronary
 18 circulation. I don't have the sales data. But I am sure
 19 that that is the case, just because of the much larger
 20 number of coronary angioplasties that are done relative
 21 to renal arteries.

22 And this was one of the first -- the
 23 Palmaz-Schatz, the two-segment stent connected with a
 24 connector member was one of the first stents that was
 25 clinically available for widespread clinical use. I

1 think that's one of the reasons why it was widely
 2 successful, it was available.

3 In terms of its basic design, I think it's --
 4 you know, it was the concept of the stent, a metal device
 5 that would hold open an artery, that that clearly is
 6 where the significant advance is found.

7 Q. Was it also one of the first stents to get approval
 8 in the United States from the FDA?

9 A. Yes.

10 Q. Was there any before it, do you know?

11 A. I think the Gianturco-Roubin stent was actually
 12 approved shortly before. I think they have different
 13 indications.

14 Q. Do you know if this stent was marketed by Cordis
 15 or J&J?

16 A. I know it was marketed by Johnson & Johnson.

17 Q. And do you have an opinion as to whether or not the
 18 marketing played any role in its success?

19 A. Well, as I said, there was a tremendous interest
 20 and enthusiasm for using stents in the coronary arteries.
 21 And clearly, that was something that was promoted by the
 22 manufacturer. So that once it became approved by the FDA,
 23 doctors knew about the device, and their enthusiasm was
 24 further piqued by having heard about it from the
 25 manufacturer.

1 That's what marketing is supposed to do.

2 Q. Do you have an opinion as to how much of the
 3 success was attributable to the original slotted tube idea
 4 and how much of it was attributable to the flexible
 5 connector member?

6 A. I think that you would have to say -- and I
 7 understand Cordis has had an expert agree with this --
 8 that it's really primarily the concept of delivering, you
 9 know, a stent to the coronary artery that allowed for the
 10 success of this, the slotted tubular stent. It was
 11 facilitated by having this connected stent. But the main
 12 portion of it, the main advance, was in having the stent
 13 be deliverable to the coronary arteries.

14 MR. UNDERHILL: Thank you, Doctor van Breda.

15 THE COURT: Members: We will take our one-hour
 16 lunch break.

17 I will just remind you during the break not to
 18 discuss the case among yourselves or with anyone else.
 19 Thank you.

20 (At this point the jury then left the
 21 courtroom.)

22 THE COURT: Do we need to meet before 2:00?

23 MR. WALLACE: Not from our end, your Honor, for
 24 a change.

25 MR. DISKANT: We have an hour.

1 THE COURT: Hard to believe!
2 (Luncheon recess taken.)
3 ---

4 AFTERNOON SESSION

5
6 (Proceedings resumed at 1:55 p.m., at sidebar,
7 outside the presence of the jury.)
8

9
10 MR. TIMMONS: Okay. The parties have come to
11 an agreement as to the outstanding exhibits that were
12 informally used during the early part of this trial. We
13 are formally admitting them now.

14 PX-13 and PX-13-A, PX-14 and PX-14-A, PX-41,
15 PX-64, which is a video and a transcript of that video,
16 PX-95, PX-122, PX-192, PX-208, PX-275, PX-276, PX-1337,
17 PX-1907, PX-2353-B, PX-2356-A, PX-3256, PX-3257, PX-3655
18 and PX-3673.

19 And there is, we're not sure -- PX-3681-A, B
20 and C have been entered. We think there is a PX-3681-D
21 and that also should be entered formally as an exhibit
22 that has been agreed upon.

23 That's all I have.

24 (End of sidebar conference.)
25 ---

1 of this morning's discussion, some of the secondary
2 considerations.

3 Q. Sure.

4 MR. DISKANT: Put X-44 up. The patent we're
5 talking about.

6 BY MR. DISKANT:

7 Q. But it's Dr. Schatz's '984 patent we're talking about;
8 correct?

9 A. Yes.

10 I honestly don't know whose name is it on it.
11 I just know it's the '984 patent.

12 MR. DISKANT: Let's pull up the name, please.

13 BY MR. DISKANT:

14 Q. Do you see Dr. Schatz's name?

15 A. Yes, it's Dr. Schatz.

16 Q. So your testimony is about Dr. Schatz's invention;
17 correct?

18 A. It's about this particular patent, yes.

19 Q. Invented by Dr. Schatz?

20 A. Okay.

21 Q. And you weren't testifying about Dr. Palmaz's
22 invention; correct?

23 A. Not directly. Just as Dr. Palmaz's earlier devices
24 pertain to the obviousness of Claims 1 and 3.

25 Q. I'd just like to be clear, and I'd like the jury to

1 (Proceedings resumed at 2:00 p.m. in the
2 courtroom.)
3

4
5 THE COURT: Is there anything before we bring
6 the jury in?

7 (There was no response.)

8 THE COURT: All right. Bring the jury in.

9 (At this point the jury entered the courtroom
10 and took their seats in the box.)

11 THE COURT: All right. Mr. Diskant, cross-
12 examination.

13 MR. DISKANT: Thank you, your Honor.

14 CROSS-EXAMINATION

15 BY MR. DISKANT:

16 Q. Good afternoon, Dr. Van Breda.

17 A. Hello.

18 Q. Just to be clear about the scope of your testimony
19 here today, you've been testifying exclusively, as I
20 understand it, about whether the Schatz '984 patent is
21 invalid for obviousness; is that right?

22 A. I'm talking specifically the only things I
23 addressed are the Claims 1 and 3 of that patent.

24 Q. Right.

25 A. As to the obviousness as well as, towards the end

1 be clear, your testimony was about your opinion about the
2 obviousness of Dr. Schatz improvement on Dr. Palmaz's
3 original work; right?

4 A. It was about this patent, yes.

5 Q. And you know Dr. Palmaz is sitting over here; is that
6 right?

7 A. Yes.

8 Q. And you knew him back in the eighties?

9 A. Yes.

10 Q. And your testimony was not about his '762 patent;
11 correct?

12 A. Correct.

13 Q. Okay. Now, you, Dr. van Breda, are not a
14 cardiologist; correct?

15 A. Correct.

16 Q. And you don't principally treat patients with
17 coronary heart disease; correct?

18 A. Correct.

19 Q. Now, in fact, the Palmaz-Schatz stent was eagerly
20 awaited by the cardiologist community; correct?

21 A. Yes.

22 Q. And they even complained about the long test
23 process with the FDA that preceded its approval?

24 A. Yes, I would say that's true.

25 Q. Because it had been approved in Europe and it was

1 taking longer for the Palmaz-Schatz stent to be approved
 2 here in the U.S.
 3 A. That's true of many devices. The FDA has made this
 4 a much longer process here than it is in Europe.
 5 Q. But cardiologists in the United States knew about
 6 the Palmaz-Schatz stent and were eager to have it in their
 7 hands?
 8 A. Yes.
 9 Q. Sure. And, as you said, the FDA is very conservative
 10 in approving medical devices?
 11 A. Mm-hmm.
 12 Q. You have to say yes or no for the record. I'm sorry.
 13 A. Yes.
 14 Q. And that conservatism is designed to protect the
 15 American public?
 16 A. Correct.
 17 Q. It's particularly conservative when it's considering
 18 a novel invention; correct?
 19 A. Yeah. I'm not sure that I would characterize the
 20 FDA as particularly conservative when it comes to a novel
 21 invention. Sometimes the ways of the FDA are a little
 22 hard to divine, but it could be characterized as
 23 conservative.
 24 Q. And there was certainly doubt in the early 1990's
 25 about whether it was safe to implant metal in the

1 Dr. Badger is a cardiologist; right?
 2 A. I'm aware of that, yes.
 3 Q. And cardiology is the principal application of the
 4 balloon expandable stent, is that fair to say?
 5 A. No. It's the principal application of the Palmaz-
 6 Schatz balloon expandable stent, but I don't know that it
 7 would be correct to say it's the principal application of
 8 the balloon expandable stent, just leaving it as that
 9 large a category.
 10 Q. Don't you know if you considered all uses of balloon
 11 expandable stents in the United States, the vast majority
 12 would be in the coronary arteries?
 13 A. I think that is probably safe to say.
 14 Q. Okay. Let me read you this question and answer
 15 from Dr. Badger and see you if you agree with it?
 16 MR. UNDERHILL: Could we have the page number
 17 and line number?
 18 MR. DISKANT: Yes. Page 1689, Line 17:
 19 "Question: Are you aware that the
 20 Stress and the Benestent trials were the
 21 pivotal trials established in -- that the
 22 balloon expandable stent provides real
 23 benefits over angioplasty?
 24 "Answer: I'm very well aware of
 25 those studies.

1 arteries near the heart, and so the FDA required
 2 extensive medical testing; is that right?
 3 A. Yes, there was some doubt. Yes.
 4 Q. And at a time when other companies were doing
 5 nothing about balloon expandable stents, Johnson &
 6 Johnson invested in the Stress and Benestent trials;
 7 correct?
 8 A. I'm not sure it's accurate to say companies were
 9 doing nothing about balloon expandable stents.
 10 Q. Okay. The Stress and Benestent trials were the
 11 largest trials done up until that time of a medical device;
 12 correct?
 13 A. Again, you pointed out, I'm not a cardiologist. I'm
 14 somewhat familiar with the cardiology literature. Those
 15 were trials done specifically for coronary applications of
 16 the Palmaz-Schatz device, so if you say they're the
 17 largest, you know, I can't say that, be willing to say
 18 that.
 19 Q. Let me ask you, were you here when Dr. Badger
 20 testified the other day for AVE?
 21 A. No, I wasn't.
 22 Q. I'd like to read you a excerpt of his testimony, ask
 23 you if you agree with it.
 24 "Question: Are you aware that the
 25 Stress" -- Excuse me.

1 "Question: And those -- those are
 2 very important studies; correct?
 3 "Answer: Very important.
 4 "Question: Changed your life; right?
 5 "Answer: Changed my life and the
 6 life of many patients.
 7 "Question: And they tested and proved
 8 that the Palmaz-Schatz balloon expandable
 9 stent provided improved benefits over
 10 angioplasty; correct?
 11 "Answer: Correct."
 12 Do you agree with that testimony?
 13 MR. UNDERHILL: Your Honor, I would ask it
 14 be placed in front of the witness, so she can look at it.
 15 THE WITNESS: It would be very hard for me to
 16 answer as to whether it changed Dr. Badger's life or not.
 17 BY MR. DISKANT:
 18 Q. Fair enough.
 19 Other than that, do you agree with the
 20 testimony? That's on the Wednesday -- excuse me. I'm
 21 giving you probably more than you need here. If you
 22 would look to the tab for Wednesday, November 15... I
 23 probably should help you.
 24 MR. DISKANT: May I approach, your Honor,
 25 just to help the witness?

1 THE COURT: Yes, you may
 2 BY MR. DISKANT:
 3 Q. I'm sorry. Wednesday, November 15, Page -- there
 4 you are.
 5 A. Okay. Thanks.
 6 Q. Striking the part about whether it changed Dr.
 7 Badger's life, would you agree with the testimony?
 8 A. Yes. I would say I agree with it basically.
 9 Q. And on Page 1696, two pages later, on these
 10 Minuscripts anyway, let me ask you about this, from Dr.
 11 Badger's testimony, Line 11:
 12 "Question: Anyway, the Palmaz-Schatz
 13 stent was approved for general commercial
 14 sale in the United States in 1994; is that
 15 correct?
 16 "Answer: That's correct.
 17 "Question: That revolutionized your
 18 practice; right?
 19 "Answer: It did.
 20 "Question: Major advance in medical
 21 history?
 22 "Answer: Major advance in medical
 23 history."
 24 Setting aside whether it revolutionized Dr.
 25 Badger's personal practice, would you agree with that

1
 2 Q. You also testified a little bit about how Johnson &
 3 Johnson's marketing had an effect on sales.
 4 Do you recall that?
 5 A. Yes.
 6 Q. All companies market their products; correct?
 7 A. Clearly.
 8 Q. And medical companies actually educate doctors on
 9 how to use new products, don't they?
 10 A. True.
 11 Q. And it is particularly important when the product
 12 is a new kind of product that doctors are completely
 13 unfamiliar with. Isn't that true?
 14 A. That's true.
 15 Q. And it may surprise the jury, but it is true that
 16 doctors don't learn everything in medical school; right?
 17 A. That is true.
 18 Q. In fact, the medical device industry is a very
 19 important source of education for doctors about how to
 20 use their devices; correct?
 21 A. Yes, that's true.
 22 Q. And you know that Johnson & Johnson, when the
 23 Palmaz-Schatz stent was approved, invested tremendous
 24 resources in training doctors around this country?
 25 A. That is true.

1 testimony?
 2 A. I mean I think major is a very -- is a very relative
 3 term. Clearly, the advent of a stent that was widely
 4 available for the treatment of coronary artery disease
 5 did enhance and improve the ability of cardiologists to
 6 treat percutaneously. Is it a major advance? It
 7 improved angioplasty, yes.
 8 Q. Okay. And again, you would defer to a cardiologist
 9 on that?
 10 A. I'm sorry?
 11 Q. You would defer to a cardiologist?
 12 A. Yes, I would have to defer to a cardiologist.
 13 ---
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

1 Q. That is because doctors around the country didn't
 2 have a clue about how to use a balloon expandable stent;
 3 correct?
 4 A. Correct.
 5 Q. So they sent physicians around the country who are
 6 experienced in the use of a balloon expandable stent
 7 teaching doctors how to use the Palmaz-Schatz stent;
 8 correct?
 9 A. Correct.
 10 Q. And then, once trained, of course, doctors make
 11 their own decisions about how to treat patients; correct?
 12 A. That's true.
 13 Q. And Johnson & Johnson doesn't tell them that?
 14 A. No.
 15 Q. And the FDA doesn't tell them that, either?
 16 A. No. The FDA give approved indications as to why --
 17 the indications for which they have approved the device.
 18 However, once the device is approved, a physician can
 19 use that device pretty much as they see fit.
 20 Q. That is commonplace; right?
 21 A. Yes, that is true.
 22 Q. So a new device might be approved for limited uses,
 23 but doctors who are experienced with it and use their own
 24 medical judgment, they use it for other, wider uses;
 25 right?

1. A. It happens frequently.
 2 MR. UNDERHILL: Your Honor, the question seems
 3 way outside the scope of direct and doesn't seem to relate
 4 at all to obviousness.
 5 THE COURT: Objection overruled.
 6 BY MR. DISKANT:
 7 Q. I think you also told us on direct that the
 8 Palmaz-Schatz stent was a tremendous commercial success;
 9 correct?
 10 A. Yes, as far as I am aware, it was.
 11 Q. When Mr. Croce was here, he told us that it had been
 12 voted by other medical experts the most important new
 13 medical device in the last 15 years.
 14 Do you have any reason to disagree with that?
 15 A. I don't know who that gentleman is, who you just
 16 referred to. I don't know who it was that said that
 17 that, the Palmaz-Schatz stent, was the most -- phrase that
 18 again, please.
 19 Q. Let me get the testimony.
 20 Okay. Doctor, Mr. Croce is the company Group
 21 Chairman of Johnson & Johnson, responsible for the Cordis
 22 business.
 23 A. Okay.
 24 Q. And he gave this testimony at -- I want to ask you
 25 about it. It's on Page 932, Line 16.

1 "Question: Has the Palmaz-Schatz
 2 stent received any awards within the
 3 medical device industry?
 4 "Answer: Yes, we did. We received
 5 one award. There is a group that they
 6 call at the Phoenix meeting they -- it's
 7 the members of this, they are invited to
 8 this meeting, rather. It's not an
 9 association. It's medical device presidents,
 10 chairmen, founders, they meet annually. A
 11 couple of years ago they decided that they
 12 should probably give out some type of
 13 recognition for individuals as well as
 14 products, and they established an award
 15 called the Most Successful New Product
 16 Introduction Award, and they sent ballots
 17 to the people that show up at these
 18 meetings and also to other industry
 19 individuals at that level. And they
 20 limited a ballot to maybe six products
 21 or five, I don't recall the number. And
 22 they had gone back to the last 15 years.
 23 And they have chosen a steering committee,
 24 what were the considered the most successful
 25 product launches. And the first time they

1 gave that award it was to the Palmaz-Schatz
 2 stent."
 3 Can you think of a more successful medical
 4 device that has been launched in the 15 years leading up
 5 to 1994?
 6 A. That would be a lot of medical devices. I am not
 7 sure what the definition of success is. I don't argue
 8 with the fact that that particular group made that decision.
 9 But I would venture to say that there were other devices
 10 that were probably of probably similar import.
 11 I can't answer that. I have to know what
 12 the universe of medical devices during that 15-year period
 13 of time was.
 14 Q. Now, the Palmaz-Schatz stent that was introduced in
 15 1994 was essentially a first-generation balloon expandable
 16 stent; is that correct?
 17 A. It was the first commercially-available balloon
 18 expandable stent. I guess that makes it first generation.
 19 Q. By definition.
 20 You testified on direct, do you have an
 21 opinion as to whether Johnson & Johnson is still selling
 22 the Palmaz-Schatz stent?
 23 A. As far as I know, that has all been taken over by
 24 Cordis.
 25 Q. You understand Cordis is owned by Johnson & Johnson?

1 A. Then it's that way.
 2 Q. Do you have an opinion --
 3 A. It's now sold by Cordis. No?
 4 Q. The Palmaz-Schatz stent is sold by Cordis?
 5 A. I know that the companies changed hands. I am not
 6 sure who is selling it these days.
 7 Q. Don't you know that Cordis stopped selling it
 8 several years ago?
 9 A. No, actually, I don't know. I am not a cardiologist.
 10 I don't use their coronary device.
 11 Q. Okay. Now, you gave some testimony about obviousness
 12 with respect to dr. Schatz's invention; correct?
 13 A. Yes.
 14 Q. I would like to just explore with you what the
 15 mental processes were by which you understood that
 16 assignment. I gather you had never done anything like
 17 that before?
 18 A. That's true.
 19 Q. Did you have an understanding that you were supposed
 20 to avoid claim citing?
 21 A. Yes.
 22 Q. And let's be clear what with they mean by that. We
 23 are sitting here in the year 2000; right?
 24 A. Yes, I believe it is 2000. I will agree with that.
 25 Q. And we are trying to imagine what someone would

1 have thought in 1988, twelve years ago; is that right?
 2 A. Right.
 3 Q. That is the mental work you are doing in your
 4 obviousness analysis?
 5 A. Right.
 6 Q. That's pretty hard, isn't it?
 7 A. Well, it's not if you look at the information, the
 8 references that I used to support my obviousness analysis,
 9 because that all carefully antedated that period of time.
 10 And this was a period when I was very actively involved
 11 with stents, with lecturing, on the lecture circuit, with
 12 multiple meetings. So I can put myself back, I can
 13 remember reasonably what kind of the milieu was like, what
 14 people were interested in talking about.
 15 Q. Are you familiar with the expression that hindsight
 16 is 20/20?
 17 A. Yes, I am familiar with that expression.
 18 Q. And the risk that you run in your analysis is that
 19 you know that the Palmaz-Schatz stent, with a single
 20 connector member, was a huge success; right? That is a
 21 risk that you run in the analysis?
 22 A. Yes, I guess that would be a risk.
 23 Q. So you have to think, while it may look obvious to
 24 me now, it wasn't obvious then. That's your mental
 25 exercise; right?

1 Q. Did there come a time in 1988 or 1987 or 1986 when
 2 you picked up the phone and said, Julio, I have been
 3 reading your articles, why don't you just take a single
 4 connector member and connect your stents, then they will
 5 be flexible? Did you ever do that?
 6 A. No, I never did.
 7 Q. In fact, you didn't have that thought in those years,
 8 did you?
 9 A. No, that actually wasn't something I was actually
 10 thinking about. I am a clinician. I am a practicing
 11 physician. My interest really was in what devices are
 12 going to be available for my patients. It was not really
 13 my charge and not my particular area of interest in doing
 14 the improvements myself.
 15 Q. So it isn't a thought that you personally had as
 16 you read Dr. Palmaz' articles and the Gianturco articles
 17 back in the eighties?
 18 A. No. I don't recall that I ever sat and thought,
 19 Geez, maybe we should do this.
 20 Q. Okay. I think you also mentioned that you are not
 21 a designer of stents; right?
 22 A. Yes.
 23 Q. And you are, in fact, not a designer of products of
 24 any sort; right?
 25 A. True.

1 A. Correct.
 2 Q. And I know you are not a designer of medical devices;
 3 right?
 4 A. Correct, I am not.
 5 Q. But would you agree that, oftentimes, the best
 6 solutions are the simplest ones?
 7 A. Yes, I think that is clearly the case.
 8 Q. And it is particularly for a device that you want
 9 to put in the body and leave there for years and years
 10 and decades, perhaps?
 11 A. Yes. That is part of what I talked about when we
 12 talked about the whole obviousness analysis. Simple is
 13 better.
 14 Q. But at the same time, sometimes it takes a great
 15 deal of mental energy and work to come up with a simple
 16 solution; correct?
 17 A. True.
 18 Q. And, in fact, back in the eighties, I think you
 19 just told us you were active in this art; correct?
 20 A. I wasn't active in designing stents. I was very
 21 actively interested in what was being done with stents,
 22 and in following the progress of stent development.
 23 Q. And you even read some of these articles by Dr.
 24 Palmaz that you talked about here today?
 25 A. Correct.

1 Q. And you don't have any patents yourself?
 2 A. Correct.
 3 Q. And you have never invented something that the
 4 Patent Office said was worth giving you a patent?
 5 A. I never asked them if I developed anything that
 6 was worth having a patent on. I was involved with the
 7 development of an angioplasty balloon that was
 8 manufactured in the 1980's. That did not have a separate
 9 patent.
 10 Q. And I guess the other problem that you have in
 11 trying to think back into the minds of those back in the
 12 eighties is, I think you told us that you are somewhat
 13 higher level of skill than one of ordinary skill; right?
 14 A. Yes, I did say that. I am not sure that it's fair
 15 to say, in the way I believe you phrased it, was the
 16 other problem that I have, I don't think it's a problem,
 17 because I was very careful to try to apply the analysis
 18 based on someone of average skill of the art.
 19 Q. But let's just understand what that issue is,
 20 whether it is a problem or not. You are extremely well
 21 educated?
 22 A. Yes. I won't argue with that.
 23 Q. And you are a great success in your chosen
 24 profession?
 25 A. I have been, very fortunately, successful.

1 Q. And you have had great experience in stents in
2 particular?
3 A. I have had a lot of experience, yes.
4 Q. And, therefore, you think smarter and know more
5 than the average physician --
6 A. I won't say that I think smarter. I think that I
7 was possessed during that period of time of probably a
8 greater than average fund of knowledge and familiarity
9 than an average physician.
10 Q. So the issue that you face in trying to put your
11 mind back twelve years and invent something, or decide
12 whether it was obvious to invent something, is you have
13 to think what someone who is less well educated and less
14 experienced than you might think; correct?
15 A. Yes. That's what I did.
16 Q. And that's not necessarily an easy exercise, either,
17 is it?
18 A. Well, I do think, though, that if you look at the
19 information that was available, and if you look at the
20 clinical problems, that even if you take into account
21 making this for an average, someone of average facility
22 with the art, that the information that was available
23 would allow one still to conclude that the claims of
24 that patent were obvious.
25 Q. Now, you started your exercise, I assume, by

1 rigid stent.
2 So the advantages here are that, by having
3 a connecting member, that allows for flexibility, you
4 have overcome the inherent disadvantage of just having a
5 single stent that is rigid. And you can treat a longer
6 area of disease.
7 Q. Well, I would like to have you focus, if you would,
8 on the design of Dr. Schatz patent. Can you tell me what
9 benefits in Dr. Schatz's design from having a single
10 connector member, say as opposed to multiple connector
11 members, are, as you understood the patent when you read
12 it?
13 A. Okay. This is something that I addressed earlier
14 this morning, which is that if you are connecting two
15 rigid bodies, two stents that are inherently rigid, and
16 you have one connector between them, you have one point
17 at which there is some flexibility.
18 If you add a second connector member, then
19 you are going to have less flexibility, or flexibility in
20 less directions than if you have a single one.
21 Q. So you understand one of the benefits of Dr. Schatz's
22 design is a single connector is more -- can give you more
23 flexibility than multiple connectors?
24 A. That would be the conclusion I would draw, thinking
25 about the clinical problems and thinking about the

1 reading the patent; is that right?
2 A. Correct.
3 Q. Was that the first patent you ever read?
4 A. I am not sure if it was the first one I ever read.
5 Certainly one of the very first.
6 Q. So you read through all its technical language?
7 A. Yes.
8 Q. And you studied the drawings?
9 A. Correct.
10 Q. And you tried to understand what Dr. Schatz at
11 least was saying his invention was all about; correct?
12 A. Yes.
13 Q. That is an essential first step before you can
14 decide whether it was obvious or not?
15 A. Yes.
16 Q. Let's just look at Figure 7, please.
17 Figure 8, I am sorry. You studied Figure 8?
18 A. Yes, I did.
19 Q. I would like you to tell me, when you analyzed Dr.
20 Schatz' design, can you tell me all the benefits of the
21 design relating to flexibility that you saw?
22 A. The benefits are that you overcome the inherent
23 disadvantage of having a single rigid stent, and having
24 to apply a single rigid stent to a long area of disease
25 when you don't have any flexibility within that single

1 description of the patent.
2 Q. Do you see any other benefits from Dr. Schatz's
3 design?
4 A. Well, the same benefits that accrue to the single
5 slotted tube design, which is something that can be
6 mounted on a balloon and expanded to a diameter that is
7 larger than the diameter that it goes into the artery.
8 Q. I am focusing on flexibility. When you studied it,
9 did you see other -- did you consider the other attributes
10 of flexibility that Dr. Schatz designed into this design?
11 A. I think that's -- the attributes of flexibility
12 accrue specifically to the connecting member.
13 Q. Did you consider any other attributes of
14 flexibility attributed to the connector member as designed
15 by Dr. Schatz?
16 A. I am not sure I understand what you are asking.
17 Q. Well, did you recognize that Dr. Schatz, by having
18 one connector member, leaves the adjacent slots in the
19 design free to flex? Do you see that in the drawing?
20 A. I am sorry. Say that again? Having one connector
21 member alleviates --
22 Q. Having a single connector member allows the slots
23 at the end of the segment to flex themselves. Do you see
24 that?
25 A. I still don't understand what you are trying to

1. describe.

2 MR. DISKANT: Can we blow up just the two

3 ends?

4 BY MR. DISKANT:

5 Q. You see a connector member, correct?

6 A. Okay.

7 Q. And what is above the connector member in the
8 illustration?

9 A. Vast open space.

10 Q. Vast open space. Does that have any benefits for
11 flexibility?

12 A. I really don't understand what you are saying. I
13 really don't understand what you are getting at here. I
14 just don't understand your question.

15 Q. You just don't understand, okay. Let me try again.

16 You see the vast open space --

17 A. If what you are saying is that by having the
18 connecting member on one side of the stent allows there to
19 be a further separation of the opposing, the opposite side
20 of the stent, because that can gap further, is that what
21 you are saying?

22 Q. No. I am actually focusing on this open space here
23 and the slot right next to the connector member. Do you
24 see that?

25 A. Yes.

1 Diskant is using that as a guise to ask about something
2 that he believes may be relevant to infringement.

3 THE COURT: At this point I am taking Mr.
4 Diskant's word for it. If it is infringement, I will
5 stop it.

6 MR. DISKANT: I am not asking about
7 infringement, your Honor.

8 BY MR. DISKANT:

9 Q. I am asking you -- I think you agree with me -- in
10 order to do your obviousness analysis, you first had to
11 understand the invention; right?

12 A. Yes.

13 Q. I am asking you about the invention, as you
14 understood it.

15 A. Correct.

16 Q. Do you understand that in Dr. Schatz's invention,
17 by having a single connector adjacent to a slot, the slot
18 would be able to bend as the stent goes around a bend?

19 A. But the same stent, the unitary stent body, will
20 have those same characteristics as it's going around a
21 bend to the degree that a single stent can go around the
22 bend.

23 ---

24

25

1 Q. And in Dr. Schatz's design, there is always that
2 open space in the slot next to the connector member;
3 correct?

4 A. Okay, yeah.

5 Q. And the slot is designed to expand and open, correct,
6 eventually --

7 A. Yes. When the balloon expands, its it opens up,
8 right.

9 Q. So it actually has flexibility in the slot; correct?

10 A. Yes. But so does the single Palmaz stent.

11 Q. Do you see that by having the connector member
12 adjacent to an open space in the slot, Dr. Schatz allows
13 the slot to bend and flex as it goes around the tortuous
14 passageways of the body?

15 MR. UNDERHILL: Your Honor, this appears to
16 go to infringement. It certainly doesn't go to
17 obviousness. I am not even sure it goes to infringement.

18 I object as being well outside the scope of direct.

19 THE COURT: Certainly this witness didn't
20 testify about --

21 MR. DISKANT: I am not asking infringement
22 questions, your Honor. I am asking whether, in deciding
23 it was obvious, did she understand what she was opining
24 about.

25 MR. UNDERHILL: Your Honor, I believe Mr.

1
2 Q. Now -- I'm sorry.

3 A. Is what you're -- is what you're referring to that
4 the alternative option would have been for Dr. Schatz to
5 have suggested connecting the stents at the slots, as
6 opposed to at the ends?

7 Q. That's another question. I'll get to that in a
8 moment.

9 A. Okay.

10 Q. I'm asking you Dr. Schatz had the idea of having a
11 series of segments; right?

12 A. Yes.

13 Q. And you have a series of segments, you have more ends;
14 right?

15 A. Correct.

16 Q. The three segments he has here have a total of six
17 ends, for example?

18 A. Okay.

19 Q. As opposed to a single unit that has two ends;
20 correct?

21 A. Correct.

22 Q. And by having a multiplicity of segments, he expands
23 the number of ends that are connected; correct?

24 A. Yes.

25 Q. And there is flexibility in the slot next to the

1. connector, right?

2 A. Yeah. I just -- I don't understand what you are
3 saying that there is flexibility in the slot next to the
4 connector. There is flexibility at the connector where
5 it connects to the stent within that connector itself. I
6 don't understand what flexibility in the slot means.

7 Q. Didn't you read in Dr. Schatz patent that the
8 design allows the tubular members to bend as well when
9 they go around the bend?

10 A. I would be glad to look at the patent again.

11 Q. Sure.

12 MR. DISKANT: Can we go to, what is the next?
13 47, 48?

14 Hold it. Pull from in here, 25 to 30, in
15 there.

16 BY MR. DISKANT:

17 Q. Are you with me, Dr. van Breda?

18 "It should be noted that connector
19 members 100 permit the bending, or
20 articulation of adjacent tubular members
21 in any direction about the longitudinal
22 axis of graft or prosthesis 70."

23 Do you see that?

24 A. Yes, it says the connector allows this.

25 Q. Yes.

Page 2170

1 A. Meaning they're bending relative to each other at
2 the connector.

3 Q. It says:

4 "The connector members permit the
5 bending of the tubular members"; right?

6 A. Yes, relative one to the other.

7 Q. Okay. Thank you.

8 MR. DISKANT: Can we go back to Figure 8,
9 please?

10 Just pull that up.

11 BY MR. DISKANT:

12 Q. Did you consider any other design benefits with
13 respect to flexibility that Dr. Schatz disclosed in this
14 design, in your obviousness analysis?

15 A. No.

16 Q. Did you consider that Dr. Schatz placed the
17 connector with the closed end of a slot?

18 MR. DISKANT: Can we blow that up, please?

19 THE WITNESS: Well, this would be quite
20 obvious. It would be extremely -- if you are going to, if
21 you assume a basic Palmaz stent and you are going to
22 connect the two rigid individual stents together, then it
23 would fly contrary to common sense and the reason to have
24 them connected in an offset manner at the slots as opposed
25 to at the closed ends of the stent.

1 BY MR. DISKANT:

2 Q. You know there are commercial products within
3 connectors running at the slots?

4 A. There may well be. This would not be what I think
5 that anyone of ordinary skill of the art would consider
6 the optimal way or the preferential way or, to go back to
7 a principle we talked about earlier, the simplest way to
8 do this. And I think that there are reasons why that
9 would not be a preferable way to do it. That this would
10 be the most obvious way to do it.

11 Q. What design benefits come from Dr. Schatz's design,
12 having the connector at the end?

13 A. The reason one would want to do this and the reason
14 why this would be the most obvious is that if you had the
15 connectors in the slots, in the portion that is set back
16 and then you had them flexing between, at the connector
17 member between the two individual bodies, what that leaves
18 you with as this bends is that, that portion of stent
19 between the slot and between the closed end would project
20 into the lumen of the artery or would potentially not be
21 opposed to the wall of the artery and, therefore, could
22 cause obstruction. This would -- there would be a
23 bunching of material as you bend the stent at the slot as
24 opposed to at the closed end.

25 Q. Can you articulate the design benefit that comes

Page 2172

1 from having a connector at the end in terms of flexibility?

2 A. I believe I just did.

3 Q. Don't you see having the connector at the end creates
4 leverage on this arm and allows the adjoining slot to open
5 when it goes around a bend?

6 A. There may be that effect. That, I would have to
7 talk to my engineering colleague, the second half of this
8 "person of average." I think that it's -- the overwhelming
9 asset of this is this is a much simpler and much more
10 obvious way to do it, and that you avoid the problem of
11 what happens with that portion between the open end and
12 the slot as the bending is occurring at the slot.

13 Q. So are you telling us I think that the benefit of
14 a lever arm at the end is not obvious to you?

15 A. Yes.

16 Q. Okay.

17 MR. DISKANT: Could we go back to the whole
18 picture again, please?

19 BY MR. DISKANT:

20 Q. Are there any other benefits in Dr. Schatz's design
21 that bear on flexibility that you noticed when you
22 reviewed this patent?

23 A. No, I think the flexible connecting member is the
24 one that is the most pertinent.

25 Q. How about the angularly offset design?

Page 2169 - Page 2172

1 A. I told you about that earlier this morning, that if
 2 one were going to connect more than two together, that
 3 the way that would be most obvious to do this and based
 4 on the prior art that was available, that the way to do
 5 that would be to have them angularly offset.
 6 Q. What are the benefits of angularly offset connectors?
 7 A. As I mentioned this morning, what angularly
 8 offsetting does is prevents this seam from occurring or
 9 the spine and allows you to have flexing in multiple
 10 directions as opposed to just a single or limited range
 11 of directions that you would if you had them all lined up
 12 in a row on one side of the circumference.
 13 Q. Okay. Now, you talked about various prior art
 14 references in your testimony this morning; is that
 15 correct?
 16 A. Correct.
 17 Q. Some of the prior art references are what you call
 18 connected Z-stents; is that right?
 19 A. Yes.
 20 MR. DISKANT: Can we have the front page of
 21 the patent, please?
 22 BY MR. DISKANT:
 23 Q. You understand that the Patent Office considered
 24 connected Z stent art in deciding to grant this patent;
 25 right?

1 the other.
 2 Q. Okay. Let me show you Plaintiff's Exhibit 100.
 3 (Counsel conferred.)
 4 BY MR. DISKANT:
 5 Q. Let me show you Plaintiff's Exhibit 100. Is this
 6 the article that is described on the page of the patent?
 7 A. Yes, it is.
 8 Q. Are you familiar with it?
 9 A. Yes, I am.
 10 MR. DISKANT: I offer Plaintiff's Exhibit
 11 100, your Honor.
 12 MR. UNDERHILL: No objection.
 13 BY MR. DISKANT:
 14 Q. This is a connected Z-stent experiment; is that
 15 right?
 16 A. Actually more accurately, it's a stent graft
 17 article.
 18 Q. Okay. And that is self-expanding?
 19 A. Yes. In this instance, I'd like to make clear
 20 we're not talking about grafts the way we were this
 21 morning when stent and graft were synonymous. In some of
 22 Dr. Palmaz's earlier articles he uses the expression
 23 "graft" and what he is really talking about is just a
 24 bare metal stent. In this instance, it's a self-expanding
 25 endovascular graft and it's a metal stent. In this case,

1 A. I know that? I'm not sure if that is the case.
 2 Oh, I see. It's listed. Actually, there is
 3 a Gianturco stent.
 4 Q. Well, that's not the one I'm pointing to.
 5 MR. DISKANT: Blow up "other publications."
 6 There is the Gianturco stent, that's true, but I'm
 7 pointing to the other publications portion. I'm sorry.
 8 I'm having technical problems.
 9 Thank you. There. We've got it.
 10 BY MR. DISKANT:
 11 Q. This is the Yosheika reference, right?
 12 A. I'm not sure what reference that is. If we have
 13 it available, I'll take a look at it.
 14 Q. Weren't you curious in forming your opinion about
 15 obviousness what the Patent Office had considered?
 16 A. Actually, what I was trying to do was to look at
 17 what someone who is of ordinary skill of the art would
 18 have used to make the determination of obviousness, and
 19 I didn't look at what the Patent Office did.
 20 Q. So is it relevant to your consideration whether
 21 the Patent Office considered the arguments you've made
 22 and granted the patent nonetheless?
 23 A. To my decision as to someone of ordinary skill in
 24 the art, I don't know what the Patent Office decided was
 25 prior art was necessarily going to affect it one way or

1 it's the Gianturco stent and the then there is a cloth
 2 covering it. I think it's a nylon covering they used in
 3 this one.
 4 MR. DISKANT: Here, why don't we look at the
 5 cover of the page for a second of PX-100?
 6 BY MR. DISKANT:
 7 Q. The authors are Yosheika and Gianturco is the last
 8 listed author; is that right?
 9 A. Okay.
 10 Q. You understand Dr. Gianturco is one of the leading
 11 experimenters terms of what we call the Z-stents?
 12 A. Yes.
 13 Q. And this is a Z-stent?
 14 A. This is a device that is used as Z-stent.
 15 Q. Okay. This is a device that used as a Z-stent.
 16 MR. DISKANT: Let's just take a look at the
 17 picture on the next page.
 18 Just blow up the photograph there.
 19 BY MR. DISKANT:
 20 Q. Okay. Now, this is the device that was considered
 21 by the Patent Office; correct?
 22 A. Yes. It's the device that is previous referenced
 23 in this article, yes.
 24 Q. And basically the way it works is the Z-stent is a
 25 device that pops open; is that right?

1. A. Yeah.
 2 Q. It doesn't use a balloon to expand?
 3 A. Correct, it's self-expanding.
 4 Q. It expands like a spring?
 5 A. Yes.
 6 Q. And it's a sheath in order to prevent it from
 7 expanding; is that right?
 8 A. That's correct, but not in this illustration.
 9 Q. On the illustration, it's partially sticking out;
 10 is that right?
 11 A. No.
 12 Q. Okay.
 13 A. Okay. What this is is a nylon graft surrounding a
 14 Z-stent. The top stent -- there are multiple Z-stents.
 15 There are actually four of them. Three within the graft
 16 portion of this -- okay? -- and then there is one that
 17 is free.
 18 Q. And the way it works is the graft portion gets
 19 withdrawn and the stent expands; is that right?
 20 A. No.
 21 Q. That's this embodiment?
 22 A. I'm sorry.
 23 Q. In this embodiment we're talking about.
 24 A. (No response.)
 25 Q. Let's go to another Z-stent just to avoid confusion.

Page 2178

- 1 A. Okay.
 2 MR. DISKANT: Can I have PX-143, please?
 3 BY MR. DISKANT:
 4 Q. I think I have a copy of an exhibit you used this
 5 morning, PX-143. Is that another article about Z-stents?
 6 A. Yes. This time it is just a Z-stent and not a
 7 stent graft as the Yosheika article referred to.
 8 Q. Okay. And let's take a look at --
 9 MR. DISKANT: I offer PX-143.
 10 MR. UNDERHILL: No objection.
 11 MR. DISKANT: It was in evidence.
 12 BY MR. DISKANT:
 13 Q. Can we go to the second page of the article and see
 14 if we can pull up the picture which I think will
 15 unfortunately be pretty poor?
 16 A. That's --
 17 Q. That's not the picture?
 18 A. That is a different stent.
 19 MR. DISKANT: It's not scanned. I'm sorry.
 20 Do you have your picture?
 21 (Counsel conferred.)
 22 MR. DISKANT: Mr. Underhill has been using the
 23 same picture I showed you a moment ago.
 24 MR. DISKANT: Let's take the picture down.
 25 Let's just talk it through for a second.

- 1 MR. UNDERHILL: Just to clarify, that picture
 2 wasn't used with this witness.
 3 MR. DISKANT: I'm sorry.
 4 MR. UNDERHILL: That picture was not used
 5 with this witness.
 6 MR. DISKANT: Okay.
 7 MR. UNDERHILL: Okay.
 8 BY MR. DISKANT:
 9 Q. The basic idea of a connected Z-stent is it pops
 10 open; correct?
 11 A. Yes.
 12 Q. And it's in a sheath?
 13 A. Well, it's in a sheath first, and the sheath is
 14 removed and then the device pops open.
 15 Q. Right. And the sheath is pulled back?
 16 A. Correct.
 17 Q. Right? And as the sheath exposes the Z stent, it
 18 pops open; correct?
 19 A. Yes.
 20 Q. And if it were not connected to the Z-stent behind
 21 it, it would have a tendency to drift away or pop away;
 22 is that right?
 23 A. No. Generally once the stent is delivered, it tends
 24 to spring out, as you said. If they're not connected, you
 25 have a potential for them to not end up contiguous to each

Page 2180

- 1 other.
 2 Q. Right. Wasn't that what PX-143 teaches, as we look
 3 at the caption?
 4 A. Yes. In Figure 1, where they have two Gianturco
 5 stents, a doubt stent connected together with a bar.
 6 Q. Right. And Presley (phonetic) teaches that:
 7 "The strut that connects them,
 8 two stents connected by a wire strut,
 9 allow a greater expansile force than a
 10 single long stent."
 11 That is because the two shorter stents will
 12 have more expansive power than one longer stent; right?
 13 A. That's correct.
 14 Q. That is what that reference?
 15 A. That is a unique feature of the Z-stent.
 16 Q. And then the other comment it says is:
 17 "And the two stents connected by
 18 a wire strut provide better stabilization
 19 during release?"
 20 A. Correct.
 21 Q. And that's referring to the fact that the wire strut
 22 connecting the two Z-stents stabilizes the stents during
 23 release.
 24 That's what it says?
 25 A. That's what it says, correct.

1 Q. And that is the purpose in the literature for the
 2 connection between the Z-stents; correct?
 3 A. In this literature, yes. That is what connector is
 4 described as doing.
 5 Q. Okay. Now I think as we discussed, Dr. Gianturco
 6 was working with the Z-stents. He was the leading
 7 proponent of them; right?
 8 A. Correct.
 9 Q. And you understand there came a time when Dr.
 10 Gianturco learned about Dr. Palmaz work with balloon
 11 expandable stents; right?
 12 A. Yes.
 13 Q. And when he learned about Dr. Palmaz's work, he
 14 didn't go to the obvious solution that Palmaz's rigidity
 15 problem was using his connector from the Z-stents to
 16 connect Palmaz stents, did he?
 17 A. I would have no way of know what Dr. Gianturco
 18 thought about solving the problem of Dr. Palmaz's stent.
 19 Q. Well, let's see what Dr. Gianturco said.
 20 MR. DISKANT: Can I have PX-2077?
 21 BY MR. DISKANT:
 22 Q. Is think this is a version of our document you
 23 testified about this morning; is that right?
 24 A. Yes.
 25 MR. DISKANT: I offer 207.

1 A. He was one person looking at them.
 2 Q. And he liked coiled stents because of their
 3 flexibility; is that right?
 4 A. I think it's safe to say he looked for the features
 5 of flexibility in coiled stents, yes.
 6 Q. And he rejected attempting to use design features
 7 to preserve the benefits of the Palmaz's design and
 8 instead moved to coil stents; right?
 9 A. Well, I don't think it's fair to say he rejected it.
 10 I think this is one manifestation of the incredible
 11 creativity and ingenuity of Dr. Gianturco's labs. In
 12 fact, he continued to work with Z-stents as well so I
 13 think he was looking at various ways of solving problems.
 14 Q. Okay. Let's just be clear on that. Dr. Gianturco
 15 worked on Z-stents which were self-expanding stents not
 16 using a balloon; right?
 17 A. Correct.
 18 Q. He looked at coil stents using a balloon; right?
 19 A. Yes.
 20 Q. And he never used, to your knowledge, a
 21 longitudinally slotted design like Dr. Palmaz's design;
 22 right?
 23 A. You mean a Z-stent?
 24 Q. No a longitudinally slotted balloon expandable stent.
 25 A. No. As far as I know, Dr. Gianturco did not use a

1 MR. UNDERHILL: No objection, your Honor.
 2 MR. DISKANT: Can we look at the front of
 3 this article, please? 7765.
 4 There we go.
 5 BY MR. DISKANT:
 6 Q. This is an article about Dr. Gianturco's design for
 7 a balloon expanded stent; is that right?
 8 A. Yes.
 9 Q. Okay.
 10 A. Well, I'm not sure it's Dr. Gian -- it's his
 11 laboratory. He is one of the authors on it.
 12 MR. DISKANT: Why don't we pull up his name
 13 on here, so we see it?
 14 THE WITNESS: He is the last author there.
 15 BY MR. DISKANT:
 16 Q. He is the last author there, Dr. Gianturco; correct?
 17 A. Correct.
 18 MR. DISKANT: Let's look at the design he was
 19 working on. It's on the same page. Pull up the lower
 20 right might be the best one.
 21 BY MR. DISKANT:
 22 Q. And this is a coil stent; is that right?
 23 A. Yes, I think that is a good way to characterize it.
 24 Q. And Dr. Gianturco is one of the leading designers
 25 of coil stents; is that right?

1 slotted stent.
 2 Q. So when Dr. Palmaz who invented and designed a
 3 stent with longitudinal slots, Dr. Gianturco did not
 4 attempt to preserve that design and make it flexible, did
 5 he?
 6 A. Not to my knowledge, no.
 7 Q. Instead, knowing about Dr. Palmaz's design, he
 8 looked for a different solution for flexibility with a
 9 coil stent; correct?
 10 A. I think he was probably looking at several
 11 different ways of addressing flexibility and this is one
 12 of them.
 13 MR. DISKANT: Let's look at what he said in
 14 his publication. I think he testified about it in the
 15 paragraph, and we have it on a demonstrative. 11737,
 16 please.
 17 BY MR. DISKANT:
 18 Q. This is the last paragraph of the article. And
 19 you testified about it this morning; correct?
 20 A. Correct.
 21 Q. And he is talking about the benefits of his coil
 22 design; right?
 23 A. Yes.
 24 Q. He says:
 25 "One definite advantage of this

1 balloon expanded stent is its
2 longitudinal flexibility."
3 Correct?
4 A. Correct.
5 Q. So he is seeing the coil as having a definite
6 advantage on flexibility; correct?
7 A. All right.
8 Q. And he then talks about Dr. Palmaz's work; correct?
9 A. Yes.
10 Q. And it says:
11 "The tubular mesh described by
12 Palmaz, et al. is also expanded by an
13 angioplasty balloon, but it lacks
14 longitudinal flexibility."
15 Correct?
16 A. Yes, that's what it says.
17 Q. So he is seeing that the original Palmaz design had
18 a problem to solve in terms of flexibility; correct?
19 A. Correct.
20 Q. And then he also said, and he talks about zig-zag
21 stents:
22 "We have also succeeded in inserting
23 the self-expanding zig-zag stents into
24 straight vessels smaller than 5 millimeters,
25 but this stent has no longitudinal

1 Q. Now, Wiktor is a coil stent; right?
2 A. Correct.
3 MR. DISKANT: Let me show you PX-99.
4 ---
5 BY MR. DISKANT:
6 Q. That is the Wiktor reference; is that right?
7 A. Correct.
8 Q. Now, let's take a look at the front page, please.
9 This is, as I said, a coil stent; right?
10 A. Yes.
11 Q. And like the typical coil stent, it has vertical
12 loops; right?
13 A. Yes.
14 Q. And vertical openings between the loops; right?
15 A. Okay.
16 Q. And that makes it different than Dr. Palmaz'
17 longitudinal slots; right?
18 A. Yes, it does.
19 Q. And you will agree with me that coil stents have
20 never been successful in the market; correct?
21 A. Not to my knowledge.
22 Q. But you said that this teaches the benefits of
23 angularly offset connector; is that right?
24 A. Yes.
25 Q. For flexibility?

1 flexibility either?"
2 A. Correct.
3 Q. Insofar as you know, Dr. Gianturco never hit upon
4 the obvious solution of preserving the benefits of Dr.
5 Palmaz's longitudinally slotted design and introducing
6 flexibility into it with a single connector; correct?
7 A. No. As far as I know, Dr. Gianturco did not
8 reproduce Dr. Palmaz's stent and then connect them
9 together.
10 Q. Even though you say that would have been an obvious
11 solution to flexibility problem; correct?
12 A. Yes.
13 Q. You also testified about the Wiktor reference; is
14 that correct?
15 A. That's correct.
16 Q. You know that was also considered by the Patent
17 Office in granting this patent?
18 A. Yes, I understand that.
19 MR. DISKANT: Can we see the front page of the
20 patent, please? X-44.
21 BY MR. DISKANT:
22 Q. Do you see where it says Wiktor up there? Okay.
23 That's the Wiktor reference, 458, the reference you were
24 talking about this morning?
25 A. Correct.

1 A. Yes.
2 Q. What you are calling connectors are these reversals
3 right here; right?
4 A. It's the part labeled No. 6.
5 Q. Yes. This part right here, where I am pointing, 6?
6 A. Right.
7 Q. You understand that those reversers, reversals in
8 the design are actually for expansion; correct?
9 A. Well, but I believe that they are also for
10 flexibility.
11 Q. Well, you know that a coil, a perfect coil like a
12 slinky is as flexible as can be; right?
13 A. Very flexible.
14 Q. And when you introduce expansion joints, you
15 actually reduce the flexibility of the stent; correct?
16 A. I am not an engineer, so I can't answer that
17 question.
18 Q. You don't know one way or the other?
19 A. No.
20 Q. But you know that the reversals are, in fact, there
21 for expansion; correct?
22 A. I know that's one of the purposes for them.
23 Q. Where do you see any other purpose?
24 A. Well, this gets back to Claim 10 on Column 6, where
25 basically, what this is describing is an expandable stent

1. with multiple stent bodies, which I take to be the loops
 2 that are incorporated under No. 2 there. And they are
 3 connected together.
 4 Q. Okay. Where does it say that is for flexibility?
 5 A. Well, going back to Column 3, it's, Line 34, the
 6 reversing loops are skewed.
 7 Q. Yes.
 8 A. And the reason for having those reversing loops
 9 skewed are to allow for uniform flexing, which means it's
 10 flexible.
 11 Q. Did you review the file wrapper of the Wiktor
 12 patent?
 13 A. I don't believe so.
 14 Q. Let me show you Defendant's Exhibit 3236, please.
 15 Do you know what a file wrapper is?
 16 A. I heard the term. I honestly don't remember what
 17 it is.
 18 Q. So your review of this question of obviousness did
 19 not include looking -- you looked at the file wrapper of
 20 the '984 patent?
 21 A. If you remind me, refresh my memory as for what a
 22 file wrapper is.
 23 Q. It is the exchanges back and forth between the
 24 applicant and the Patent Office in connection with the
 25 grant of a patent.

Page 2190

1 A. You know, I honestly don't remember if I reviewed
 2 that for this particular patent.
 3 Q. Did you review it for the '984 patent?
 4 A. You know, I don't remember.
 5 Q. Let me direct your attention to the top of Page 4.
 6 Are you with me?
 7 A. Yes.
 8 MR. UNDERHILL: We would object, unless the
 9 entire file wrapper is placed in front of the witness.
 10 She has already said that she hasn't seen this document
 11 before.
 12 MR. DISKANT: Let me use it to refresh
 13 recollection.
 14 THE COURT: That is permissible.
 15 BY MR. DISKANT:
 16 Q. Does looking at the document I provided you assist
 17 your recollection with respect to the purpose of using
 18 alternate coils wound in opposite directions?
 19 A. I see that.
 20 Q. And what is the purpose of having the coils wound
 21 in opposite directions?
 22 A. It's to prevent radial expansion of the stent.
 23 Q. Now, you also talked about some of Dr. Palmaz's own
 24 work; right?
 25 A. Correct.

1 Q. And, you know that Dr. Palmaz didn't like the idea
 2 of a -- what you say is the obvious idea of a single
 3 connector?
 4 A. I don't know whether Dr. Palmaz liked that idea or
 5 not.
 6 Q. You understand that many doctors, many cardiologists
 7 were very skeptical of the idea of a single connector
 8 because they feared it would result in prolapse?
 9 A. I am aware that that was a concern.
 10 Q. And if a design doesn't work, it's not exactly an
 11 obvious solution, is it?
 12 A. No, I don't think that that is necessarily the case.
 13 You mean if -- an obvious solution can be an obvious
 14 solution. Until that obvious solution is tried, you don't
 15 know whether or not it is going to work.
 16 Q. What you call an obvious solution that many people
 17 think won't work is not necessarily an obvious solution,
 18 is it?
 19 A. Well, first, it's not clear that all people thought
 20 that it wouldn't work. And I don't know the reasons why
 21 Dr. Palmaz didn't think that it would not work. And
 22 whether or not the issue of prolapse -- that doesn't
 23 really affect obviousness or not.
 24 The clinical problem that was being addressed
 25 at that point in time was trying to get a rigid stent

Page 2192

1 into a curved artery, and the consideration of prolapse,
 2 while a real one, was of lesser concern, I think, at
 3 that point in time to those individuals interested in the
 4 development of stents than the issue of flexibility.
 5 Q. Let me direct -- I would like to read you an
 6 excerpt from Dr. Badger's testimony here yesterday and
 7 see if you agree with it or not. From Page 1736, but I
 8 will read it.
 9 Dr. Badger is AVE's cardiologist expert; is
 10 that right?
 11 A. I am aware of who Dr. Badger is.
 12 I am sorry, give me the page number again,
 13 please?
 14 Q. Page 1736, in the same transcript you were just
 15 looking at.
 16 A. Okay.
 17 "Question: And there was a lot
 18 of skepticism about whether Dr. Schatz's
 19 design would work?
 20 "Answer: There was skepticism as
 21 to whether there would be problems with
 22 this gap between the two boxcars, yes,
 23 there was."
 24 Do you agree with that?
 25 A. That's what it says.

1 Q. Do you agree with it?
 2 A. Yes. There was skepticism about the issue of a gap.
 3 Q. And that skepticism was eventually resolved by
 4 large-scale clinical testing; correct?
 5 A. I think that skepticism as to whether or not the
 6 device would work was largely addressed by those clinical
 7 trials.

8 MR. DISKANT: Nothing else, your Honor.

9 THE COURT: I would like to take our afternoon
 10 break. 15 minutes, ladies and gentlemen of the jury.
 11 (At this point the jury then left the
 12 courtroom.)

13 THE COURT: All right.

14 (Short recess taken.)

15 ---

1 Is the Charson Galvitch article on the face of
 2 the '984 patent?
 3 A. No, it's not.
 4 Q. Do you know if these articles were never submitted
 5 to the Patent and Trademark Office?
 6 A. I don't know.
 7 Q. And you also gave extensive testimony about DX-1224.
 8 This is the Palmaz article that you testified was where
 9 he said that once you used rigid stents in tandem.
 10 Do you recall that article?

11 A. Yes.
 12 Q. Can you tell by looking at the '984 patent whether
 13 that article appears on the face of the '984 patent?
 14 A. That is the 1985 article; right?

15 Q. Yes, ma'am.
 16 A. No, it doesn't.
 17 Q. Do you know if this article was withheld from the
 18 Patent Office?

19 A. I don't know.
 20 Q. And you have also testified about the Yosheika
 21 reference; correct?

22 A. Yes.
 23 Q. And do you know if in -- strike that.

24 With respect to the Yosheika article, if I
 25 could have that up there, it's DX-438, do you know if

1
 2 (Court resumed after the recess.)
 3
 4 THE COURT: Anything before we bring the jury
 5 back?

6 MR. UNDERHILL: No, your Honor.

7 THE COURT: All right.

8 (At this point the jury entered the courtroom
 9 and took their seats in the box.)

10 THE COURT: Mr. Underhill, redirect.
 11 REDIRECT EXAMINATION

12 BY MR. UNDERHILL:

13 Q. I just have a few questions.

14 First of all, there were some questions from
 15 Mr. Diskant about some of the prior art that is listed on
 16 the '984 patent. I have a few questions about the prior
 17 art that is not listed on the '984 patent.

18 Specifically, you had given testimony in your
 19 direct case with respect to the Wallace connected Z-stent
 20 article that we have right here. Is that on the face of
 21 the '984 patent?

22 A. No, it's not.

23 Q. This will be the Charson Galvitch (phonetic) article
 24 that you testified about, a connected Z-stent article
 25 about which you gave substantial testimony earlier.

1 Dr. Schatz, in seeking a patent, told the Patent Office
 2 that this article was not prior art?
 3 A. I don't know what statement he might have made
 4 about that one way or the other.

5 Q. Now, let's look at the picture in Yosheika, if we
 6 could, please.

7 A. Sure.

8 MR. UNDERHILL: If you could blow that up...

9 BY MR. UNDERHILL:

10 Q. I think Mr. Diskant at one point referred to this as
 11 a sheath; is that correct?

12 A. I believe he did refer to it. It is not.

13 Q. You have actually used these devices, haven't you?

14 A. Yes.

15 Q. And could you explain --

16 A. I don't use this specific device. I have used
 17 devices similar to this.

18 Q. You have used connected Z-stents?

19 A. I have used connected Z-stents and I have also used
 20 a stent graft.

21 Q. Could you explain to us what this is?

22 A. That is the graft portion of a stent graft. As I
 23 tried to be careful about earlier, a graft is a term that
 24 is used somewhat loosely earlier in the Palmaz articles,
 25 where he is talking about a graft and he just talking

1 about bare metal.
2 That is now, what we would call nowadays -- we
3 would call it clinically a stent.
4 A stent graft is you start with a scaffolding,
5 a metal stent, on top of that a piece of graft material,
6 some kind of fabric material, nylon, all kinds of synthetic
7 materials, and you literally sew that graft material onto
8 the scaffolding of the metal stent and you have a combined
9 system.

10 What that shows is not a sheath; that shows
11 a graft. That's the graft material on the three lower
12 elements of the -- the three lower stent segments.

13 ---
14
15
16
17
18
19
20
21
22
23
24
25

1 and formerly an employee of Cordis.

2 ---

3 ... DEBRA M. SHAVER, having been
4 duly sworn as a witness, was examined
5 and testified as follows ...

6 DIRECT EXAMINATION

7 BY MR. WALLACE:

8 Q. Ms. Shaver would you tell the jury where you live?

9 A. I live in San Jose California with my husband.

10 Q. And where do you work?

11 A. I work at AVE.

12 Q. And what do you do?

13 A. I sell AVE stents.

14 Q. And I take it you're familiar with the MicroStent 2,
15 the GFX and GFX 2?

16 A. Yes. I sold all three of those stents.

17 Q. Would you tell the jury when you joined AVE?

18 A. I joined AVE in October of 1997.

19 Q. And what were you doing before that?

20 A. Prior to that I worked for Cordis Corporation.

21 Q. And would explain to the jury what did you at Cordis?

22 A. I worked at Cordis from 1991 until '97.

23 From '91 until 1996 I was a coronary sales
24 representative.

25 And then from '96 to '97, I was professional

Page 2198

Page 2200

1
2 Q. There was testimony that you gave with respect to
3 skepticism. Could you describe for us the reaction to
4 the potentiality of placing stents in the coronary
5 arteries?
6 A. Yes. And I -- I think I talked about that this
7 morning. There was a tremendous interest in the
8 possibility of putting stents in the coronary arteries.
9 And that was evident at any of the national meetings
10 where these devices were discussed as national radiology
11 meetings, national cardiology meetings. Literally,
12 there would be standing room only during the stent
13 sessions.

14 MR. UNDERHILL: I have no further questions.
15 Thank you, your Honor.

16 MR. DISKANT: Nothing, your Honor.

17 THE COURT: All right. You may step down.
18 Thank you.

19 THE WITNESS: Thank you.
20 (Witness excused)
21 ---

22 MR. WALLACE: Your Honor, I'm very happy to
23 be able to announce we are prepared to call our last
24 witness in our case. Debra Shaver please.

25 Debra Shaver is currently an employee of AVE

1 education manager based out of the Southeast.
2 Q. And would you explain to the jury what your
3 responsibilities were in the two different positions you
4 held?

5 A. As a sales rep for Cordis, I was responsible for
6 calling on cardiac cath labs and cardiologists and
7 interventional cardiologists selling a full line of
8 catheters, balloons, steerable guidewires, guiding
9 catheters, as well as intracoronary ultrasound we had
10 through an agreement with another company.

11 When I held the position of Professional
12 Education Manager, I was responsible for the sales
13 training and development of new sales reps. Also
14 responsible for the management of advanced coronary
15 stent courses we put on in the Southeast, and the Palmaz
16 stent training courses that we put on in conjunction
17 with the OSNA Clinic.

18 Q. And did you receive any awards from Cordis while
19 you worked there?

20 A. In 1997, I was -- or 1994, I was sales
21 representative of the year. I received two marketing
22 Eagle awards for sales performance in steerable
23 guidewires and guiding catheters. And in 1996, I
24 received the Presidential Leadership award.

25 Q. Would you explain to the jury what the Presidential

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☐ FADED TEXT OR DRAWING

☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.